EXHIBIT B

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Al-Ali

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(54) **PHYSIOLOGICAL MEASUREMENT DEVICES, SYSTEMS, AND METHODS**

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(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

This patent is subject to a terminal disclaimer.

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(58) **Field of Classification Search**
None
See application file for complete search history.

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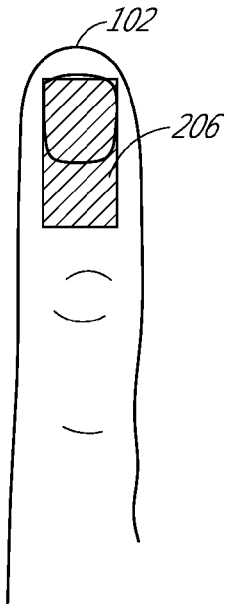
(57) **ABSTRACT**

A non-invasive, optical-based physiological monitoring system is disclosed. One embodiment includes an emitter configured to emit light. A diffuser is configured to receive and spread the emitted light, and to emit the spread light at a tissue measurement site. The system further includes a concentrator configured to receive the spread light after it has been attenuated by or reflected from the tissue measurement site. The concentrator is also configured to collect and concentrate the received light and to emit the concentrated light to a detector. The detector is configured to detect the concentrated light and to transmit a signal representative of the detected light. A processor is configured to receive the transmitted signal and to determine a physiological parameter, such as, for example, arterial oxygen saturation, in the tissue measurement site.

25 Claims, 7 Drawing Sheets



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Mar. 25, 2020 First Amended Complaint for (1) Patent Infringement (2) Trade Secret Misappropriation (3) Correction of Inventorship and (4) Ownership of Patents and Demand for Jury Trial, and including Exhibits 13-24 (Exhibits 1-12 and 25-31 comprise copies of publicly available U.S. patents and U.S. patent application publications, and are not included herein for ease of transmission), *Masimo Corporation*and *Cercacor Laboratories, Inc.*v. *Apple Inc.*, Case No. 8:20-cv-00048, pp. 1-94, 983-1043 (total of 156 pages).

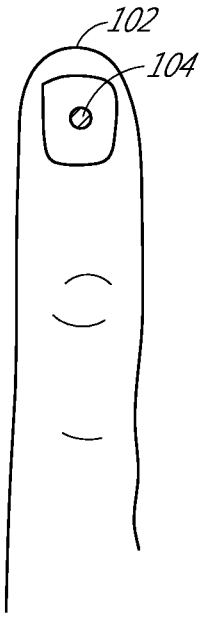

FIG. 1
(PRIOR ART)

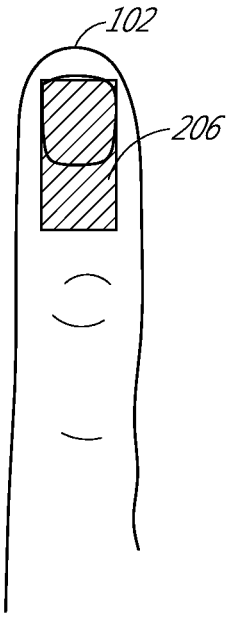

FIG. 2

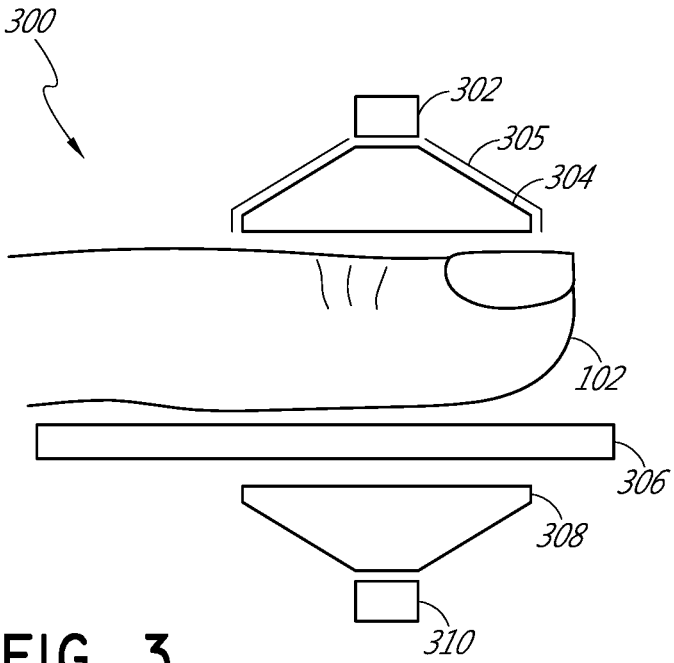

FIG. 3

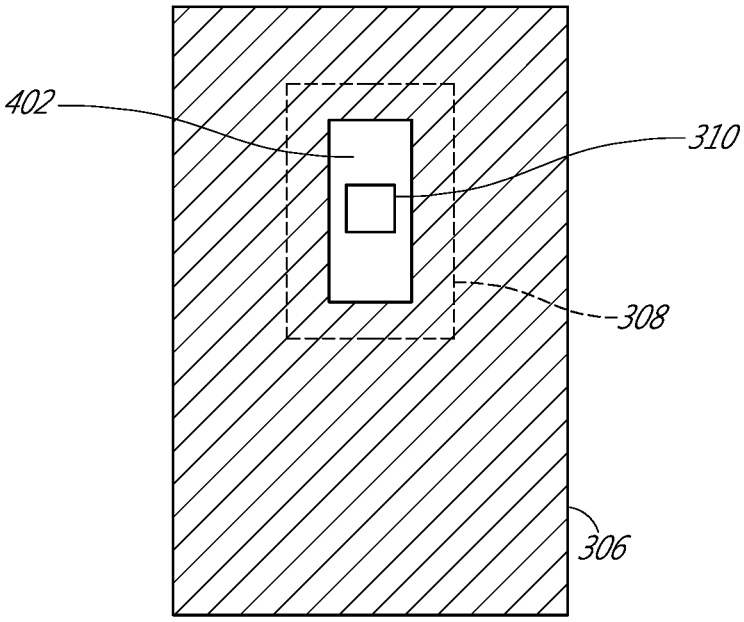

FIG. 4A

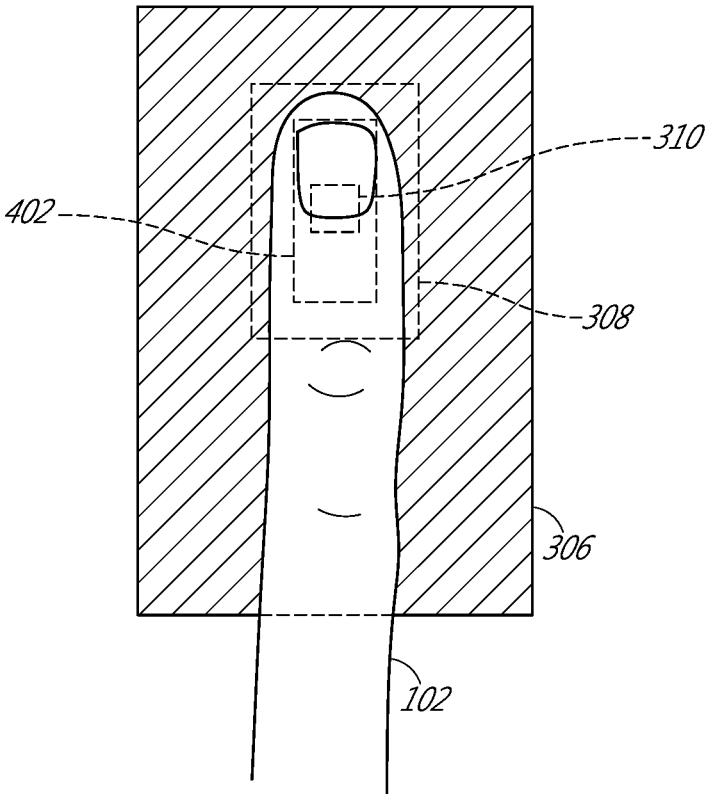

FIG. 4B

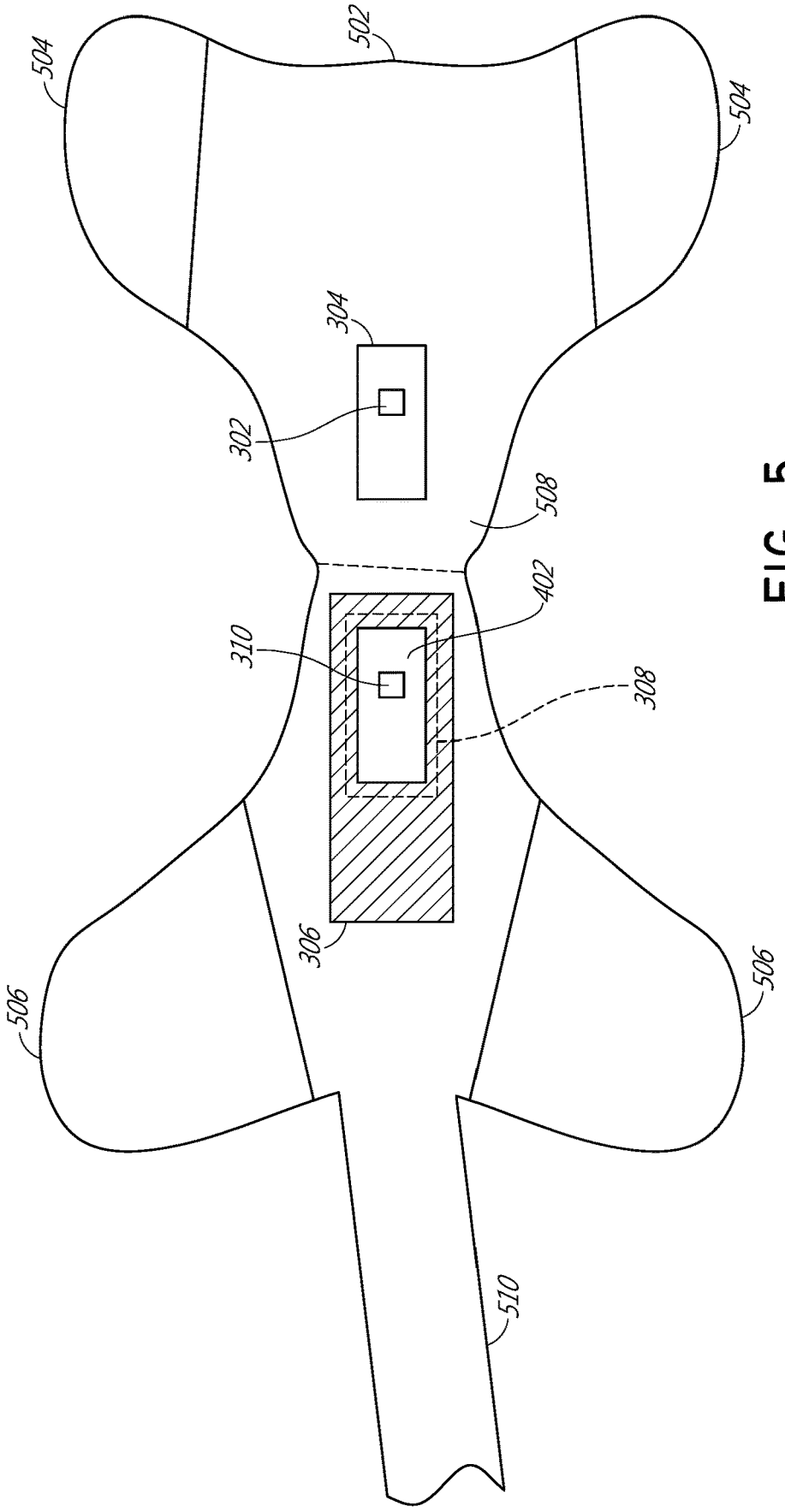

FIG. 5

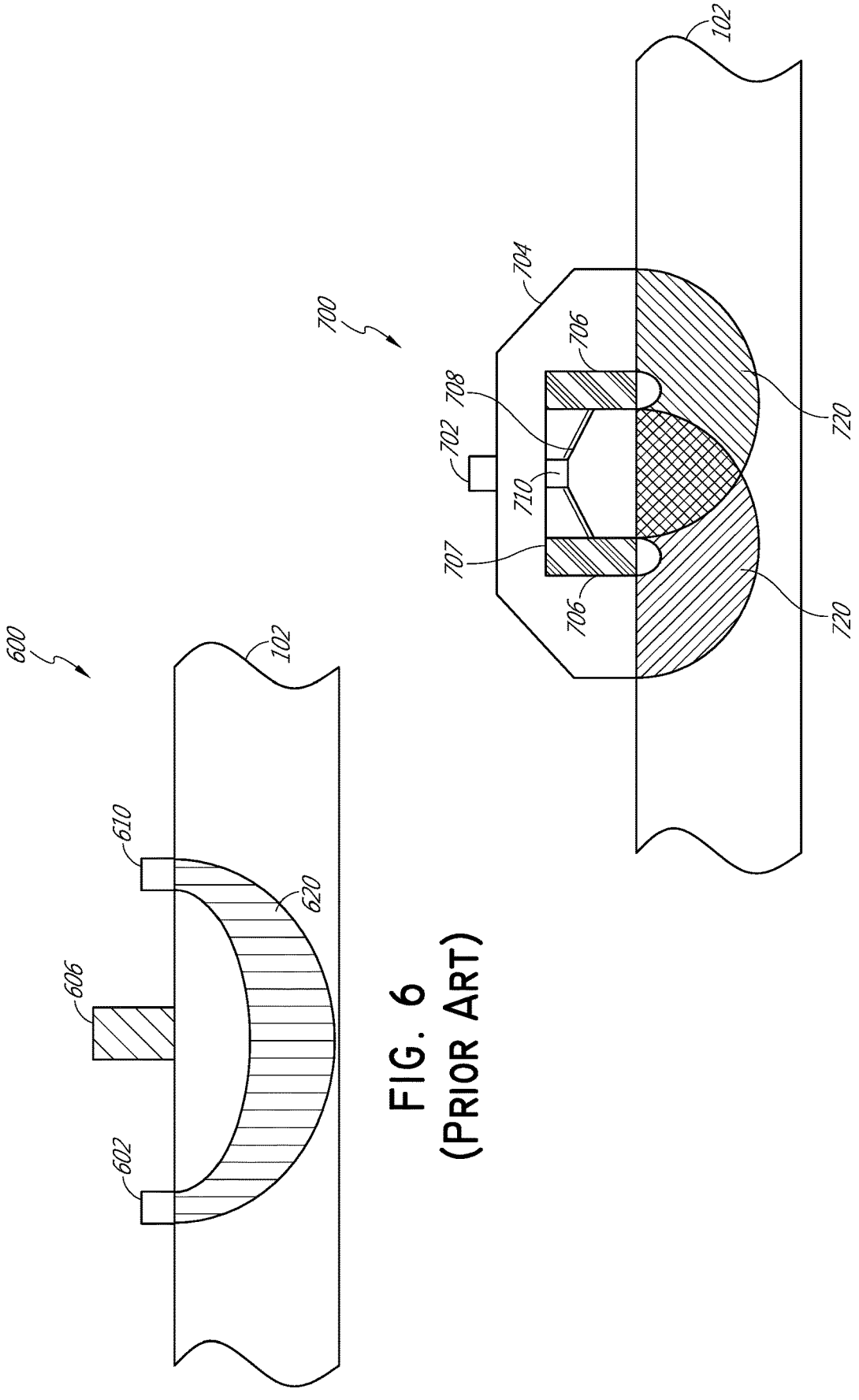

FIG. 7A

FIG. 6
(PRIOR ART)

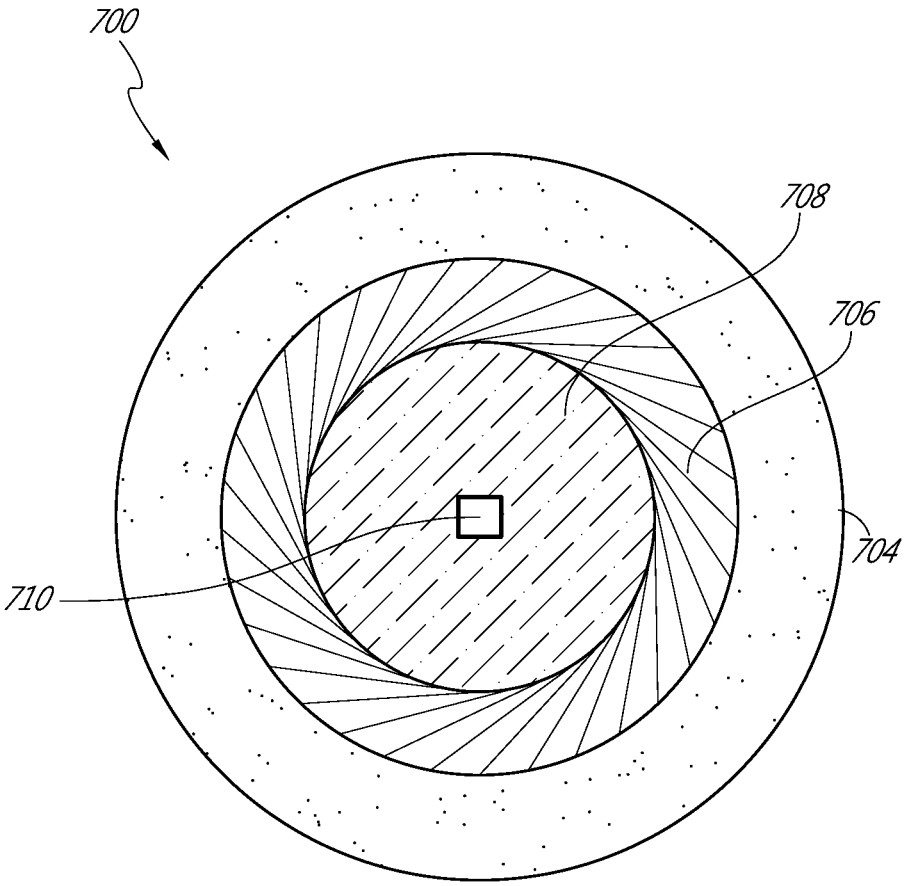

FIG. 7B

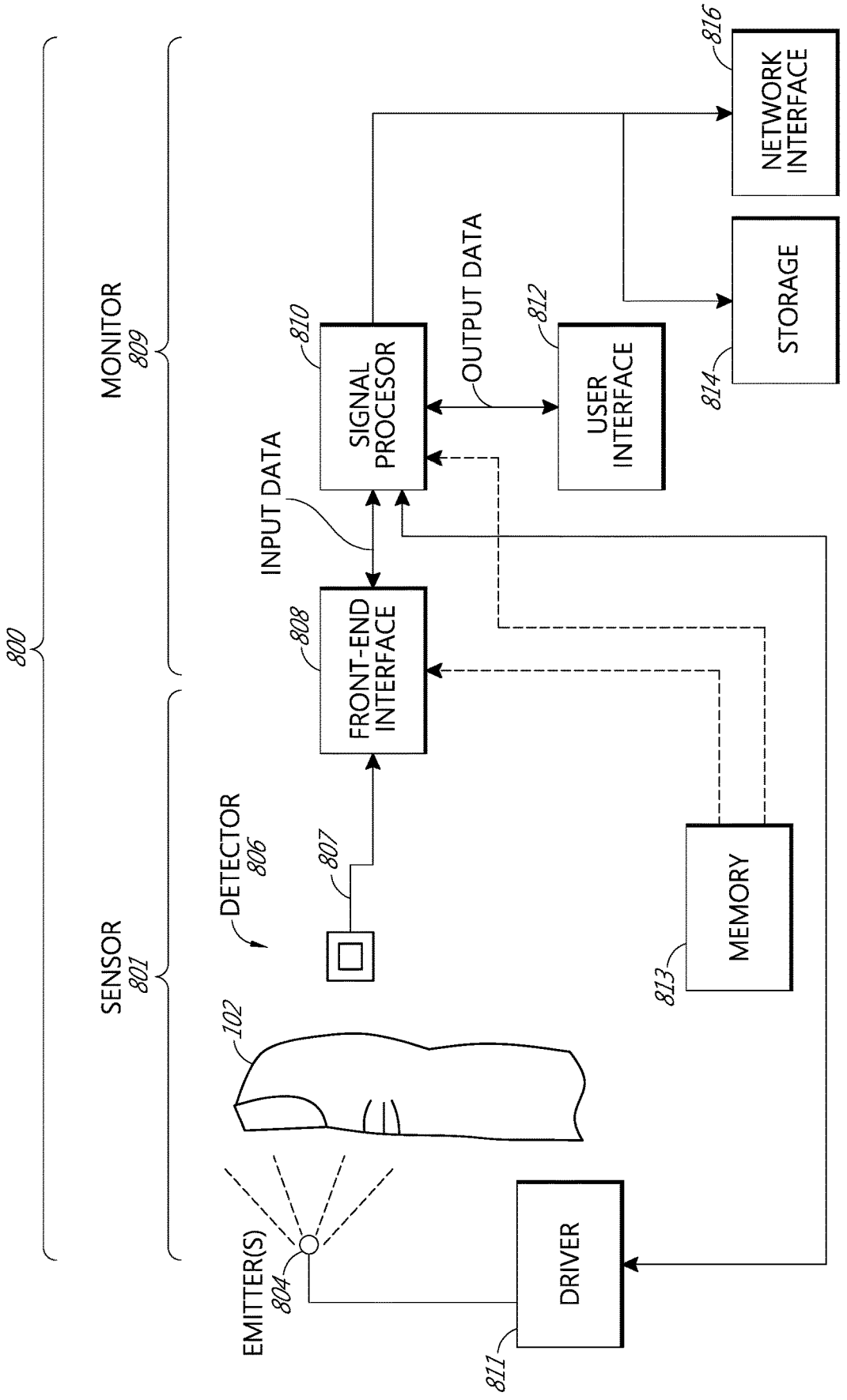
800
MONITOR
809
SENSOR
801
SIGNAL PROCESOR
810
USER INTERFACE
812
NETWORK INTERFACE
816
STORAGE
814
OUTPUT DATA
INPUT DATA
FRONT-END INTERFACE
808
DETECTOR
806
807
MEMORY
813
102
EMITTER(S)
804
DRIVER
811

FIG. 8

PHYSIOLOGICAL MEASUREMENT DEVICES, SYSTEMS, AND METHODS

INCORPORATION BY REFERENCE TO ANY PRIORITY APPLICATIONS

The present application is a continuation of U.S. patent application Ser. No. 16/532,061 filed Aug. 5, 2019, which is a continuation of U.S. patent application Ser. No. 15/195,199 filed Jun. 28, 2016, which claims priority benefit under 35 U.S.C. § 119(e) from U.S. Provisional Application No. 62/188,430, filed Jul. 2, 2015, which is incorporated by reference herein. Any and all applications for which a foreign or domestic priority claim is identified in the Application Data Sheet as filed with the present application are hereby incorporated by reference under 37 CFR 1.57.

FIELD OF THE DISCLOSURE

The present disclosure relates to the field of non-invasive optical-based physiological monitoring sensors, and more particularly to systems, devices and methods for improving the non-invasive measurement accuracy of oxygen saturation, among other physiological parameters.

BACKGROUND

Spectroscopy is a common technique for measuring the concentration of organic and some inorganic constituents of a solution. The theoretical basis of this technique is the Beer-Lambert law, which states that the concentration c_i of an absorbent in solution can be determined by the intensity of light transmitted through the solution, knowing the path-length d_λ, the intensity of the incident light $I_{0,\lambda}$, and the extinction coefficient $\varepsilon_{i,\lambda}$ at a particular wavelength λ.

In generalized form, the Beer-Lambert law is expressed as:

$$I_\lambda = I_{0,\lambda} e^{-d_\lambda \cdot \mu_{\alpha,\lambda}} \quad (1)$$

$$\mu_{a,\lambda} = \sum_{i=1}^{n} \varepsilon_{i,\lambda} \cdot c_i \quad (2)$$

where $\mu_{\alpha,\lambda}$ is the bulk absorption coefficient and represents the probability of absorption per unit length. The minimum number of discrete wavelengths that are required to solve equations 1 and 2 is the number of significant absorbers that are present in the solution.

A practical application of this technique is pulse oximetry, which utilizes a noninvasive sensor to measure oxygen saturation and pulse rate, among other physiological parameters. Pulse oximetry relies on a sensor attached externally to the patient to output signals indicative of various physiological parameters, such as a patient's blood constituents and/or analytes, including for example a percent value for arterial oxygen saturation, among other physiological parameters. The sensor has an emitter that transmits optical radiation of one or more wavelengths into a tissue site and a detector that responds to the intensity of the optical radiation after absorption by pulsatile arterial blood flowing within the tissue site. Based upon this response, a processor determines the relative concentrations of oxygenated hemoglobin (HbO_2) and deoxygenated hemoglobin (Hb) in the blood so as to derive oxygen saturation, which can provide early detection of potentially hazardous decreases in a patient's oxygen supply.

A pulse oximetry system generally includes a patient monitor, a communications medium such as a cable, and/or a physiological sensor having one or more light emitters and a detector, such as one or more light-emitting diodes (LEDs) and a photodetector. The sensor is attached to a tissue site, such as a finger, toe, earlobe, nose, hand, foot, or other site having pulsatile blood flow which can be penetrated by light from the one or more emitters. The detector is responsive to the emitted light after attenuation or reflection by pulsatile blood flowing in the tissue site. The detector outputs a detector signal to the monitor over the communication medium. The monitor processes the signal to provide a numerical readout of physiological parameters such as oxygen saturation (SpO2) and/or pulse rate. A pulse oximetry sensor is described in U.S. Pat. No. 6,088,607 entitled Low Noise Optical Probe; pulse oximetry signal processing is described in U.S. Pat. Nos. 6,650,917 and 6,699,194 entitled Signal Processing Apparatus and Signal Processing Apparatus and Method, respectively; a pulse oximeter monitor is described in U.S. Pat. No. 6,584,336 entitled Universal/Upgrading Pulse Oximeter; all of which are assigned to Masimo Corporation, Irvine, Calif., and each is incorporated by reference herein in its entirety.

There are many sources of measurement error introduced to pulse oximetry systems. Some such sources of error include the pulse oximetry system's electronic components, including emitters and detectors, as well as chemical and structural physiological differences between patients. Another source of measurement error is the effect of multiple scattering of photons as the photons pass through the patient's tissue (arterial blood) and arrive at the sensor's light detector.

SUMMARY

This disclosure describes embodiments of non-invasive methods, devices, and systems for measuring blood constituents, analytes, and/or substances such as, by way of non-limiting example, oxygen, carboxyhemoglobin, methemoglobin, total hemoglobin, glucose, proteins, lipids, a percentage thereof (e.g., saturation), pulse rate, perfusion index, oxygen content, total hemoglobin, Oxygen Reserve Index™ (ORI™) or for measuring many other physiologically relevant patient characteristics. These characteristics can relate to, for example, pulse rate, hydration, trending information and analysis, and the like.

In an embodiment, an optical physiological measurement system includes an emitter configured to emit light of one or more wavelengths. The system also includes a diffuser configured to receive the emitted light, to spread the received light, and to emit the spread light over a larger tissue area than would otherwise be penetrated by the emitter directly emitting light at a tissue measurement site. The tissue measurement site can include, such as, for example, a finger, a wrist, or the like. The system further includes a concentrator configured to receive the spread light after it has been attenuated by or reflected from the tissue measurement site. The concentrator is also configured to collect and concentrate the received light and to emit the concentrated light to a detector. The detector is configured to detect the concentrated light and to transmit a signal indicative of the detected light. The system also includes a processor configured to receive the transmitted signal indicative of the detected light and to determine, based on an

amount of absorption, an analyte of interest, such as, for example, arterial oxygen saturation or other parameter, in the tissue measurement site.

In certain embodiments of the present disclosure, the diffuser comprises glass, ground glass, glass beads, opal glass, or a microlens-based, band-limited, engineered diffuser that can deliver efficient and uniform illumination. In some embodiments the diffuser is further configured to define a surface area shape by which the emitted spread light is distributed onto a surface of the tissue measurement site. The defined surface area shape can include, by way of non-limiting example, a shape that is substantially rectangular, square, circular, oval, or annular, among others.

According to some embodiments, the optical physiological measurement system includes an optical filter having a light-absorbing surface that faces the tissue measurement site. The optical filter also has an opening that is configured to allow the spread light, after being attenuated by the tissue measurement site, to be received by the concentrator. In an embodiment, the opening has dimensions, wherein the dimensions of the opening are similar to the defined surface area shape by which the emitted spread light is distributed onto the surface of the tissue measurement site. In an embodiment, the opening has dimensions that are larger than the defined surface area shape by which the emitted spread light is distributed onto the surface of the tissue measurement site. In other embodiments, the dimensions of the opening in the optical filter are not the same as the diffuser opening, but the dimensions are larger than the detector package.

In other embodiments of the present disclosure, the concentrator comprises glass, ground glass, glass beads, opal glass, or a compound parabolic concentrator. In some embodiments the concentrator comprises a cylindrical structure having a truncated circular conical structure on top. The truncated section is adjacent the detector. The light concentrator is structured to receive the emitted optical radiation, after reflection by the tissue measurement site, and to direct the reflected light to the detector.

In accordance with certain embodiments of the present disclosure, the processor is configured to determine an average level of the light detected by the detector. The average level of light is used to determine a physiological parameter in the tissue measurement site.

According to another embodiment, a method to determine a constituent or analyte in a patient's blood is disclosed. The method includes emitting, from an emitter, light of at least one wavelength; spreading, with a diffuser, the emitted light and emitting the spread light from the diffuser to a tissue measurement site; receiving, by a concentrator, the spread light after the spread light has been attenuated by the tissue measurement site; concentrating, by the concentrator, the received light and emitting the concentrated light from the concentrator to a detector; detecting, with the detector, the emitted concentrated light; transmitting, from the detector, a signal responsive to the detected light; receiving, by a processor, the transmitted signal responsive to the detected light; and processing, by the processor, the received signal responsive to the detected light to determine a physiological parameter.

In some embodiments, the method to determine a constituent or analyte in a patient's blood includes filtering, with a light-absorbing detector filter, scattered portions of the emitted spread light. According to an embodiment, the light-absorbing detector filter is substantially rectangular in shape and has outer dimensions in the range of approximately 1-5 cm in width and approximately 2-8 cm in length, and has an opening through which emitted light may pass, the opening having dimensions in the range of approximately 0.25-3 cm in width and approximately 1-7 cm in length. In another embodiment, the light-absorbing detector filter is substantially square in shape and has outer dimensions in the range of approximately 0.25-10 cm^2, and has an opening through which emitted light may pass, the opening having dimensions in the range of approximately 0.1-8 cm^2. In yet another embodiment, the light-absorbing detector filter is substantially rectangular in shape and has outer dimensions of approximately 3 cm in width and approximately 6 cm in length, and has an opening through which emitted light may pass, the opening having dimensions of approximately 1.5 cm in width and approximately 4 cm in length.

In still other embodiments of the method to determine a constituent or analyte in a patient's blood, spreading, with a diffuser, the emitted light and emitting the spread light from the diffuser to a tissue measurement site is performed by at least one of a glass diffuser, a ground glass diffuser, a glass bead diffuser, an opal glass diffuser, and an engineered diffuser. In some embodiments the emitted spread light is emitted with a substantially uniform intensity profile. And in some embodiments, emitting the spread light from the diffuser to the tissue measurement site includes spreading the emitted light so as to define a surface area shape by which the emitted spread light is distributed onto a surface of the tissue measurement site.

According to yet another embodiment, a pulse oximeter is disclosed. The pulse oximeter includes an emitter configured to emit light at one or more wavelengths. The pulse oximeter also includes a diffuser configured to receive the emitted light, to spread the received light, and to emit the spread light directed at a tissue measurement sight. The pulse oximeter also includes a detector configured to detect the emitted spread light after being attenuated by or reflected from the tissue measurement site and to transmit a signal indicative of the detected light. The pulse oximeter also includes a processor configured to receive the transmitted signal and to process the received signal to determine an average absorbance of a blood constituent or analyte in the tissue measurement site over a larger measurement site area than can be performed with a point light source or point detector. In some embodiments, the diffuser is further configured to define a surface area shape by which the emitted spread light is distributed onto a surface of the tissue measurement site, and the detector is further configured to have a detection area corresponding to the defined surface area shape by which the emitted spread light is distributed onto the surface of the tissue measurement site. According to some embodiments, the detector comprises an array of detectors configured to cover the detection area. In still other embodiments, the processor is further configured to determine an average of the detected light.

For purposes of summarizing, certain aspects, advantages and novel features of the disclosure have been described herein. It is to be understood that not necessarily all such advantages can be achieved in accordance with any particular embodiment of the systems, devices and/or methods disclosed herein. Thus, the subject matter of the disclosure herein can be embodied or carried out in a manner that achieves or optimizes one advantage or group of advantages as taught herein without necessarily achieving other advantages as can be taught or suggested herein.

BRIEF DESCRIPTION OF THE DRAWINGS

Throughout the drawings, reference numbers can be reused to indicate correspondence between referenced ele-

ments. The drawings are provided to illustrate embodiments of the disclosure described herein and not to limit the scope thereof.

FIG. **1** illustrates a conventional approach to two-dimensional pulse oximetry in which the emitter is configured to emit optical radiation as a point optical source.

FIG. **2** illustrates the disclosed three-dimensional approach to pulse oximetry in which the emitted light irradiates a substantially larger volume of tissue as compared to the point source approach described with respect to FIG. **1**.

FIG. **3** illustrates schematically a side view of a three-dimensional pulse oximetry sensor according to an embodiment of the present disclosure.

FIG. **4**A is a top view of a portion of a three-dimensional pulse oximetry sensor according to an embodiment of the present disclosure.

FIG. **4**B illustrates the top view of a portion of the three-dimensional pulse oximetry sensor shown in FIG. **4**A, with the addition of a tissue measurement site in operational position.

FIG. **5** illustrates a top view of a three-dimensional pulse oximetry sensor according to an embodiment of the present disclosure.

FIG. **6** illustrates a conventional two-dimensional approach to reflective pulse oximetry in which the emitter is configured to emit optical radiation as a point optical source.

FIG. **7**A is a simplified schematic side view illustration of a reflective three-dimensional pulse oximetry sensor according to an embodiment of the present disclosure.

FIG. **7**B is a simplified schematic top view illustration of the three-dimensional reflective pulse oximetry sensor of FIG. **7**A.

FIG. **8** illustrates a block diagram of an example pulse oximetry system capable of noninvasively measuring one or more blood analytes in a monitored patient, according to an embodiment of the disclosure.

DETAILED DESCRIPTION

FIG. **1** illustrates schematically a conventional pulse oximetry sensor having a two-dimensional (2D) approach to pulse oximetry. As illustrated, the emitter **104** is configured to emit optical radiation as a point optical source, i.e., an optical radiation source that has negligible dimensions such that it may be considered as a point. This approach is referred to herein as "two-dimensional" pulse oximetry because it applies a two-dimensional analytical model to the three-dimensional space of the tissue measurement site **102** of the patient. Point optical sources feature a defined, freely selectable, and homogeneous light beam area. Light beams emitted from LED point sources often exhibit a strong focus which can produce a usually sharply-defined and evenly-lit illuminated spot often with high intensity dynamics. Illustratively, when looking at the surface of the tissue measurement site **102** (or "sample tissue"), which in this example is a finger, a small point-like surface area of tissue **204** is irradiated by a point optical source. In some embodiments, the irradiated circular area of the point optical source is in the range between 8 and 150 microns. Illustratively, the emitted point optical source of light enters the tissue measurement site **102** as a point of light. As the light penetrates the depth of the tissue **102**, it does so as a line or vector, representing a two-dimensional construct within a three-dimensional structure, namely the patient's tissue **102**.

Use of a point optical source is believed to reduce variability in light pathlength which would lead to more accurate oximetry measurements. However, in practice, photons do not travel in straight paths. Instead, the light particles scatter, bouncing around between various irregular objects (such as, for example, red blood cells) in the patient's blood. Accordingly, photon pathlengths vary depending on, among other things, their particular journeys through and around the tissue at the measurement site **102**. This phenomenon is referred to as "multiple scattering." In a study, the effects of multiple scattering were examined by comparing the results of photon diffusion analysis with those obtained using an analysis based on the Beer-Lambert law, which neglects multiple scattering in the determination of light pathlength. The study found that that the difference between the average lengths of the paths traveled by red and infrared photons makes the oximeter's calibration curve (based on measurements obtained from normal subjects) sensitive to the total attenuation coefficients of the tissue in the two wavelength bands used for pulse oximetry, as well as to absorption by the pulsating arterial blood.

FIG. **2** illustrates schematically the disclosed systems, devices, and methods to implement three-dimensional (3D) pulse oximetry in which the emitted light irradiates a larger volume of tissue at the measurement site **102** as compared to the 2D point optical source approach described with respect to FIG. **1**. In an embodiment, again looking at the surface of the tissue measurement site **102**, the irradiated surface area **206** of the measurement site **102** is substantially rectangular in shape with dimensions in the range of approximately 0.25-3 cm in width and approximately 1-6 cm in length. In another embodiment, the irradiated surface area **206** of the measurement site **102** is substantially rectangular in shape and has dimensions of approximately 1.5 cm in width and approximately 2 cm in length. In another embodiment, the irradiated surface area **206** of the measurement site **102** is substantially rectangular in shape and has dimensions of approximately 0.5 cm in width and approximately 1 cm in length. In another embodiment, the irradiated surface area **206** of the measurement site **102** is substantially rectangular in shape has dimensions of approximately 1 cm in width and approximately 1.5 cm in length. In yet another embodiment, the irradiated surface area **206** of the measurement site **102** is substantially square in shape and has dimensions in a range of approximately 0.25-9 cm^2. In certain embodiments, the irradiated surface area **206** of the measurement site **102** is within a range of approximately 0.5-2 cm in width, and approximately 1-4 cm in length. Of course a skilled artisan will appreciate that many other shapes and dimensions of irradiated surface area **206** can be used. Advantageously, by irradiating the tissue measurement site **102** with a surface area **206**, the presently disclosed systems, devices, and methods apply a three-dimensional analytical model to the three-dimensional structure being measured, namely, the patient's sample tissue **102**.

According to the Beer-Lambert law, the amount of light absorbed by a substance is proportional to the concentration of the light-absorbing substance in the irradiated solution (i.e., arterial blood). Advantageously, by irradiating a larger volume of tissue **102**, a larger sample size of light attenuated (or reflected) by the tissue **102** is measured. The larger, 3D sample provides a data set that is more representative of the complete interaction of the emitted light as it passes through the patient's blood as compared to the 2D point source approach described above with respect to FIG. **1**. By taking an average of the detected light, as detected over a surface area substantially larger than a single point, the disclosed pulse oximetry systems, devices, and methods will yield a

more accurate measurement of the emitted light absorbed by the tissue, which will lead to a more accurate oxygen saturation measurement.

FIG. **3** illustrates schematically a side view of a pulse oximetry 3D sensor **300** according to an embodiment of the present disclosure. In the illustrated embodiment, the 3D sensor **300** irradiates the tissue measurement site **102** and detects the emitted light, after being attenuated by the tissue measurement site **102**. In other embodiments, for example, as describe below with respect to FIGS. **7**A and **7**B, the 3D sensor **300** can be arranged to detect light that is reflected by the tissue measurement site **102**. The 3D sensor **300** includes an emitter **302**, a light diffuser **304**, a light-absorbing detector filter **306**, a light concentrator **308**, and a detector **310**. In some optional embodiments, the 3D sensor **300** further includes a reflector **305**. The reflector **305** can be a metallic reflector or other type of reflector. Reflector **305** can be a coating, film, layer or other type of reflector. The reflector **305** can serve as a reflector to prevent emitted light from emitting out of a top portion of the light diffuser **304** such that light from the emitter **302** is directed in the tissue rather than escaping out of a side or top of the light diffuser **304**. Additionally, the reflector **305** can prevent ambient light from entering the diffuser **304** which might ultimately cause errors within the detected light. The reflector **305** also prevent light piping that might occur if light from the detector **302** is able to escape from the light diffuser **304** and be pipped around a sensor securement mechanism to detector **310** without passing through the patient's tissue **102**.

The emitter **302** can serve as the source of optical radiation transmitted towards the tissue measurement site **102**. The emitter **302** can include one or more sources of optical radiation, such as LEDs, laser diodes, incandescent bulbs with appropriate frequency-selective filters, combinations of the same, or the like. In an embodiment, the emitter **302** includes sets of optical sources that are capable of emitting visible and near-infrared optical radiation. In some embodiments, the emitter **302** transmits optical radiation of red and infrared wavelengths, at approximately 650 nm and approximately 940 nm, respectively. In some embodiments, the emitter **302** includes a single source optical radiation.

The light diffuser **304** receives the optical radiation emitted from the emitter **302** and spreads the optical radiation over an area, such as the area **206** depicted in FIG. **2**. In some embodiments, the light diffuser **304** is a beam shaper that can homogenize the input light beam from the emitter **302**, shape the output intensity profile of the received light, and define the way (e.g., the shape or pattern) the emitted light is distributed to the tissue measurement site **102**. Examples of materials that can be used to realize the light diffuser **304** include, without limitation, a white surface, glass, ground glass, glass beads, polytetrafluoroethylene (also known as Teflon®, opal glass, and greyed glass, to name a few. Additionally, engineered diffusers can be used to realize the diffuser **304** by providing customized light shaping with respect to intensity and distribution. Such diffusers can, for example, deliver substantially uniform illumination over a specified target area (such as, for example, irradiated surface area **206**) in an energy-efficient manner. Examples of engineered diffusers can include molded plastics with specific shapes, patterns or textures designed to diffuse the emitter light across the entirety of the patient's tissue surface.

Advantageously, the diffuser **304** can receive emitted light in the form of a point optical source and spread the light to fit a desired surface area on a plane defined by the surface of the tissue measurement site **102**. In an embodiment, the diffuser **304** is made of ground glass which spreads the emitted light with a Gausian intensity profile. In another embodiment the diffuser **304** includes glass beads. In some embodiments, the diffuser **304** is constructed so as to diffuse the emitted light in a Lambertian pattern. A Lambertian pattern is one in which the radiation intensity is substantially constant throughout the area of dispersion. One such diffuser **304** is made from opal glass. Opal glass is similar to ground glass, but has one surface coated with a milky white coating to diffuse light evenly. In an embodiment, the diffuser **304** is capable of distributing the emitted light on the surface of a plane (e.g., the surface of the tissue measurement site **102**) in a predefined geometry (e.g., a rectangle, square, or circle), and with a substantially uniform intensity profile and energy distribution. In some embodiments, the efficiency, or the amount of light transmitted by the diffuser **304**, is greater than 70% of the light emitted by the emitter **302**. In some embodiments, the efficiency is greater than 90% of the emitted light. Other optical elements known in the art may be used for the diffuser **304**.

In an embodiment, the diffuser **304** has a substantially rectangular shape having dimensions within a range of approximately 0.5-2 cm in width and approximately 1-4 centimeters in length. In another embodiment, the substantially rectangular shape of the diffuser **304** has dimensions of approximately 0.5 cm in width and approximately 1 cm in length. In another embodiment, the diffuser's **304** substantially rectangular shape has dimensions of approximately 1 cm in width and approximately 1.5 cm in length. In yet another embodiment, the diffuser **304** has a substantially square shape with dimensions in the range of approximately 0.25-10 cm^2.

The light-absorbing detector filter **306**, which is also depicted in FIG. **4**A in a top view, is a planar surface having an opening **402** through which the emitted light may pass after being attenuated by the tissue measurement site **102**. In the depicted embodiment, the opening **402** is rectangular-shaped, with dimensions substantially similar to the irradiated surface area **206**. According to an embodiment, the light-absorbing detector filter is substantially rectangular in shape and has outer dimensions of 4 cm in width and 8 cm in length, and has an opening through which emitted light may pass, the opening having dimensions of 2 cm in width and 5 cm in length. In another embodiment, the light-absorbing detector filter is substantially rectangular in shape and has outer dimensions in the range of 1-3 cm in width and 2-8 cm in length, and has an opening through which emitted light may pass, the opening having dimensions in the range of 0.25-2 cm in width and 1-4 cm in length. In yet another embodiment, the light-absorbing detector filter is substantially rectangular in shape and has outer dimensions of 3 cm in width and 6 cm in length, and has an opening through which emitted light may pass, the opening having dimensions of 1.5 cm in width and 4 cm in length.

The top surface of the light-absorbing filter **306** (facing the tissue measurement site **102** and the emitter **302**) is coated with a material that absorbs light, such as, for example, black pigment. Many other types of light-absorbing materials are well known in the art and can be used with the detector filter **306**. During operation, light emitted from the emitter **302** can reflect off of the tissue measurement site **102** (or other structures within the 3D sensor **300**) to neighboring portions of the 3D sensor **300**. If those neighboring portions of the 3D sensor **300** possess reflective surfaces, then the light can reflect back to the tissue measurement site **102**, progress through the tissue and arrive at the detector **310**. Such multiple scattering can result in detecting photons whose pathlengths are considerably lon-

ger than most of the light that is detected, thereby introducing variations in pathlength which will affect the accuracy of the measurements of the pulse oximetry 3D sensor **300**. Advantageously, the light-absorbing filter **306** reduces or eliminates the amount of emitted light that is reflected in this manner because it absorbs such reflected light, thereby stopping the chain of scattering events. In certain embodiments, the sensor-facing surfaces of other portions of the 3D sensor **300** are covered in light-absorbing material to further decrease the effect of reflective multiple scattering.

The light concentrator **308** is a structure to receive the emitted optical radiation, after attenuation by the tissue measurement site **102**, to collect and concentrate the dispersed optical radiation, and to direct the collected and concentrated optical radiation to the detector **310**. In an embodiment, the light concentrator **308** is made of ground glass or glass beads. In some embodiments, the light concentrator **308** includes a compound parabolic concentrator.

As described above with respect to FIG. **1**, the detector **310** captures and measures light from the tissue measurement site **102**. For example, the detector **310** can capture and measure light transmitted from the emitter **302** that has been attenuated by the tissue in the measurement site **102**. The detector **310** can output a detector signal responsive to the light captured or measured. The detector **310** can be implemented using one or more photodiodes, phototransistors, or the like. In addition, a plurality of detectors **310** can be arranged in an array with a spatial configuration corresponding to the irradiated surface area **206** to capture the attenuated or reflected light from the tissue measurement site.

Referring to FIG. **4**A, a top view of a portion of the 3D sensor **300** is provided. The light-absorbing detector filter **306** is illustrated having a top surface coated with a light-absorbing material. The light-absorbing material can be a black opaque material or coating or any other dark color or coating configured to absorb light. Additionally, a rectangular opening **402** is positioned relative to the light concentrator **308** (shown in phantom) and the detector **310** such that light may pass through the rectangular opening **402**, into the light concentrator **308**, and to the detector **310**. FIG. **4**B illustrates the top view of a portion of the 3D sensor **300** as in FIG. **4**A, with the addition of the tissue measurement site **102** in operational position. Accordingly, the rectangular opening **402**, the light concentrator **308** and the detector **310** are shown in phantom as being under the tissue measurement site **102**. In FIGS. **4**A and **4**B, the light concentrator **308** is shown to have dimensions significantly larger than the dimensions of the rectangular opening **402**. In other embodiments, the dimensions of the light concentrator **308**, the rectangular opening **402**, and the irradiated surface area **206** are substantially similar.

FIG. **5** illustrates a top view of a 3D pulse oximetry sensor **500** according to an embodiment of the present disclosure. The 3D sensor **500** is configured to be worn on a patient's finger **102**. The 3D sensor **500** includes an adhesive substrate **502** having front flaps **504** and rear flaps **506** extending outward from a center portion **508** of the 3D sensor **500**. The center portion **508** includes components of the 3D pulse oximetry sensor **300** described with respect to FIGS. **3**, **4**A and **4**B. On the front side of the adhesive substrate **502** the emitter **302** and the light diffuser **304** are positioned. On the rear side of the adhesive substrate **502** the light-absorbent detector filter **306**, the light concentrator **308** and the detector **310** are positioned. In use, the patient's finger serving as the tissue measurement site **102** is positioned over the rectangular opening **402** such that when the front portion of the adhesive substrate is folded over on top of the patient's finger **102**, the emitter **302** and the light diffuser **304** are aligned with the measurement site **102**, the filter **306**, the light concentrator **308** and the detector **310**. Once alignment is established, the front and rear flaps **504**, **506** can be wrapped around the finger measurement site **102** such that the adhesive substrate **502** provides a secure contact between the patient's skin and the 3D sensor **500**. FIG. **5** also illustrates an example of a sensor connector cable **510** which is used to connect the 3D sensor **500** to a monitor **809**, as described with respect to FIG. **8**.

FIG. **6** is a simplified schematic illustration of a conventional, 2D approach to reflective pulse oximetry in which the emitter is configured to emit optical radiation as a point optical source. Reflective pulse oximetry is a method by which the emitter and detector are located on the same side of the tissue measurement site **102**. Light is emitted into a tissue measurement site **102** and attenuated. The emitted light passes into the tissue **102** and is then reflected back to the same side of the tissue measurement site **102** as the emitter. As illustrated in FIG. **6**, a depicted reflective 2D pulse oximetry sensor **600** includes an emitter **602**, a light block **606**, and a detector **610**. The light block **606** is necessary because the emitter **602** and the detector **610** are located on the same side of the tissue measurement site **102**. Accordingly, the light block **606** prevents incident emitter light, which did not enter the tissue measurement site **102**, from arriving at the detector **610**. The depicted 2D pulse oximetry sensor **600** is configured to emit light as a point source. As depicted in FIG. **6**, a simplified illustration of the light path **620** of the emitted light from the emitter **602**, through the tissue measurement site **102**, and to the detector **610** is provided. Notably, a point source of light is emitted, and a point source of light is detected. As discussed above with respect to FIG. **1**, use of a point optical source can result in substantial measurement error due to pathlength variability resulting from the multiple scatter phenomenon. The sample space provided by a 2D point optical emitter source is not large enough to account for pathlength variability, which will skew measurement results.

FIGS. **7**A and **7**B are simplified schematic side and top views, respectively, of a 3D reflective pulse oximetry sensor **700** according to an embodiment of the present disclosure. In the illustrated embodiment, the 3D sensor **700** irradiates the tissue measurement site **102** and detects the emitted light that is reflected by the tissue measurement site **102**. The 3D sensor **700** can be placed on a portion of the patient's body that has relatively flat surface, such as, for example a wrist, because the emitter **702** and detector **710** are on located the same side of the tissue measurement site **102**. The 3D sensor **700** includes an emitter **702**, a light diffuser **704**, a light block **706**, a light concentrator **708**, and a detector **710**.

As previously described, the emitter **702** can serve as the source of optical radiation transmitted towards the tissue measurement site **102**. The emitter **702** can include one or more sources of optical radiation. Such sources of optical radiation can include LEDs, laser diodes, incandescent bulbs with appropriate frequency-selective filters, combinations of the same, or the like. In an embodiment, the emitter **702** includes sets of optical sources that are capable of emitting visible and near-infrared optical radiation. In some embodiments, the emitter **702** transmits optical radiation of red and infrared wavelengths, at approximately 650 nm and approximately 940 nm, respectively. In some embodiments, the emitter **702** includes a single source of optical radiation.

The light diffuser **704** receives the optical radiation emitted from the emitter **702** and homogenously spreads the optical radiation over a wide, donut-shaped area, such as the

area outlined by the light diffuser **704** as depicted in FIG. **7**B. Advantageously, the diffuser **704** can receive emitted light in the form of a 2D point optical source (or any other form) and spread the light to fit the desired surface area on a plane defined by the surface of the tissue measurement site **102**. In an embodiment, the diffuser **704** is made of ground glass or glass beads. A skilled artisan will understand that may other materials can be used to make the light diffuser **704**.

The light blocker **706** includes an annular ring having a cover portion **707** sized and shaped to form a light isolation chamber for the light concentrator **708** and the detector **710**. (For purposes of illustration, the light block cover **707** is not illustrated in FIG. **7**B.) The light blocker **706** and the cover **707** can be made of any material that optically isolates the light concentrator **708** and the detector **710**. The light isolation chamber formed by the light blocker **706** and cover **707** ensures that the only light detected by the detector **710** is light that is reflected from the tissue measurement site.

The light concentrator **708** is a cylindrical structure with a truncated circular conical structure on top, the truncated section of which of which is adjacent the detector **710**. The light concentrator **708** is structured to receive the emitted optical radiation, after reflection by the tissue measurement site **102**, and to direct the reflected light to the detector **710**. In an embodiment, the light concentrator **708** is made of ground glass or glass beads. In some embodiments, the light concentrator **708** includes a compound parabolic concentrator.

As previously described, the detector **710** captures and measures light from the tissue measurement site **102**. For example, the detector **710** can capture and measure light transmitted from the emitter **702** that has been reflected from the tissue in the measurement site **102**. The detector **710** can output a detector signal responsive to the light captured or measured. The detector **710** can be implemented using one or more photodiodes, phototransistors, or the like. In addition, a plurality of detectors **710** can be arranged in an array with a spatial configuration corresponding to the irradiated surface area depicted in FIG. **7**B by the light concentrator **708** to capture the reflected light from the tissue measurement site.

Advantageously, the light path **720** illustrated in FIG. **7**A depicts a substantial sample of reflected light that enter the light isolation chamber formed by the light blocker **706** and cover **707**. As previously discussed, the large sample of reflected light (as compared to the reflected light collected using the 2D point optical source approach) provides the opportunity to take an average of the detected light, to derive a more accurate measurement of the emitted light absorbed by the tissue, which will lead to a more accurate oxygen saturation measurement.

Referring now to FIG. **7**B, a top view of the 3D sensor **700** is illustrated with both the emitter **702** and the light blocker cover **707** removed for ease of illustration. The outer ring illustrates the footprint of the light diffuser **704**. As light is emitted from the emitter **702** (not shown in FIG. **7**B), it is diffused homogenously and directed to the tissue measurement site **102**. The light blocker **706** forms the circular wall of a light isolation chamber to keep incident light from being sensed by the detector **710**. The light blocker cover **707** blocks incidental light from entering the light isolation chamber from above. The light concentrator **708** collects the reflected light from the tissue measurement site **102** and funnels it upward toward the detector **710** at the center of the 3D sensor **700**.

FIG. **8** illustrates an example of an optical physiological measurement system **800**, which may also be referred to herein as a pulse oximetry system **800**. In certain embodiments, the pulse oximetry system **800** noninvasively measures a blood analyte, such as oxygen, carboxyhemoglobin, methemoglobin, total hemoglobin, glucose, proteins, lipids, a percentage thereof (e.g., saturation), pulse rate, perfusion index, oxygen content, total hemoglobin, Oxygen Reserve Index™ (ORI™) or many other physiologically relevant patient characteristics. These characteristics can relate to, for example, pulse rate, hydration, trending information and analysis, and the like. The system **800** can also measure additional blood analytes and/or other physiological parameters useful in determining a state or trend of wellness of a patient.

The pulse oximetry system **800** can measure analyte concentrations at least in part by detecting optical radiation attenuated by tissue at a measurement site **102**. The measurement site **102** can be any location on a patient's body, such as a finger, foot, earlobe, wrist, forehead, or the like.

The pulse oximetry system **800** can include a sensor **801** (or multiple sensors) that is coupled to a processing device or physiological monitor **809**. In an embodiment, the sensor **801** and the monitor **809** are integrated together into a single unit. In another embodiment, the sensor **801** and the monitor **809** are separate from each other and communicate with one another in any suitable manner, such as via a wired or wireless connection. The sensor **801** and monitor **809** can be attachable and detachable from each other for the convenience of the user or caregiver, for ease of storage, sterility issues, or the like.

In the depicted embodiment shown in FIG. **8**, the sensor **801** includes an emitter **804**, a detector **806**, and a front-end interface **808**. The emitter **804** can serve as the source of optical radiation transmitted towards measurement site **102**. The emitter **804** can include one or more sources of optical radiation, such as light emitting diodes (LEDs), laser diodes, incandescent bulbs with appropriate frequency-selective filters, combinations of the same, or the like. In an embodiment, the emitter **804** includes sets of optical sources that are capable of emitting visible and near-infrared optical radiation.

The pulse oximetry system **800** also includes a driver **811** that drives the emitter **804**. The driver **111** can be a circuit or the like that is controlled by the monitor **809**. For example, the driver **811** can provide pulses of current to the emitter **804**. In an embodiment, the driver **811** drives the emitter **804** in a progressive fashion, such as in an alternating manner. The driver **811** can drive the emitter **804** with a series of pulses for some wavelengths that can penetrate tissue relatively well and for other wavelengths that tend to be significantly absorbed in tissue. A wide variety of other driving powers and driving methodologies can be used in various embodiments. The driver **811** can be synchronized with other parts of the sensor **801** to minimize or reduce jitter in the timing of pulses of optical radiation emitted from the emitter **804**. In some embodiments, the driver **811** is capable of driving the emitter **804** to emit optical radiation in a pattern that varies by less than about 10 parts-per-million.

The detector **806** captures and measures light from the tissue measurement site **102**. For example, the detector **806** can capture and measure light transmitted from the emitter **804** that has been attenuated or reflected from the tissue at the measurement site **102**. The detector **806** can output a detector signal **107** responsive to the light captured and measured. The detector **806** can be implemented using one

or more photodiodes, phototransistors, or the like. In some embodiments, a detector **806** is implemented in detector package to capture and measure light from the tissue measurement site **102** of the patient. The detector package can include a photodiode chip mounted to leads and enclosed in an encapsulant. In some embodiments, the dimensions of the detector package are approximately 2 square centimeters. In other embodiments, the dimensions of the detector package are approximately 1.5 centimeters in width and approximately 2 centimeters in length.

The front-end interface **808** provides an interface that adapts the output of the detectors **806**, which is responsive to desired physiological parameters. For example, the front-end interface **808** can adapt the signal **807** received from the detector **806** into a form that can be processed by the monitor **809**, for example, by a signal processor **810** in the monitor **809**. The front-end interface **808** can have its components assembled in the sensor **801**, in the monitor **809**, in a connecting cabling (if used), in combinations of the same, or the like. The location of the front-end interface **808** can be chosen based on various factors including space desired for components, desired noise reductions or limits, desired heat reductions or limits, and the like.

The front-end interface **808** can be coupled to the detector **806** and to the signal processor **810** using a bus, wire, electrical or optical cable, flex circuit, or some other form of signal connection. The front-end interface **808** can also be at least partially integrated with various components, such as the detectors **806**. For example, the front-end interface **808** can include one or more integrated circuits that are on the same circuit board as the detector **806**. Other configurations can also be used.

As shown in FIG. **8**, the monitor **909** can include the signal processor **810** and a user interface, such as a display **812**. The monitor **809** can also include optional outputs alone or in combination with the display **812**, such as a storage device **814** and a network interface **816**. In an embodiment, the signal processor **810** includes processing logic that determines measurements for desired analytes based on the signals received from the detector **806**. The signal processor **810** can be implemented using one or more microprocessors or sub-processors (e.g., cores), digital signal processors, application specific integrated circuits (ASICs), field programmable gate arrays (FPGAs), combinations of the same, and the like.

The signal processor **810** can provide various signals that control the operation of the sensor **801**. For example, the signal processor **810** can provide an emitter control signal to the driver **811**. This control signal can be useful in order to synchronize, minimize, or reduce jitter in the timing of pulses emitted from the emitter **804**. Accordingly, this control signal can be useful in order to cause optical radiation pulses emitted from the emitter **804** to follow a precise timing and consistent pattern. For example, when a transimpedance-based front-end interface **808** is used, the control signal from the signal processor **810** can provide synchronization with an analog-to-digital converter (ADC) in order to avoid aliasing, cross-talk, and the like. As also shown, an optional memory **813** can be included in the front-end interface **808** and/or in the signal processor **810**. This memory **813** can serve as a buffer or storage location for the front-end interface **808** and/or the signal processor **810**, among other uses.

The user interface **812** can provide an output, e.g., on a display, for presentation to a user of the pulse oximetry system **800**. The user interface **812** can be implemented as a touch-screen display, a liquid crystal display (LCD), an organic LED display, or the like. In alternative embodiments, the pulse oximetry system **800** can be provided without a user interface **812** and can simply provide an output signal to a separate display or system.

The storage device **814** and a network interface **816** represent other optional output connections that can be included in the monitor **809**. The storage device **814** can include any computer-readable medium, such as a memory device, hard disk storage, EEPROM, flash drive, or the like. The various software and/or firmware applications can be stored in the storage device **814**, which can be executed by the signal processor **810** or another processor of the monitor **809**. The network interface **816** can be a serial bus port (RS-232/RS-485), a Universal Serial Bus (USB) port, an Ethernet port, a wireless interface (e.g., WiFi such as any 802.1x interface, including an internal wireless card), or other suitable communication device(s) that allows the monitor **809** to communicate and share data with other devices. The monitor **809** can also include various other components not shown, such as a microprocessor, graphics processor, or controller to output the user interface **812**, to control data communications, to compute data trending, or to perform other operations.

Although not shown in the depicted embodiment, the pulse oximetry system **800** can include various other components or can be configured in different ways. For example, the sensor **801** can have both the emitter **804** and detector **806** on the same side of the tissue measurement site **102** and use reflectance to measure analytes.

Although the foregoing disclosure has been described in terms of certain preferred embodiments, many other variations than those described herein will be apparent to those of ordinary skill in the art.

Conditional language used herein, such as, among others, "can," "might," "may," "e.g.," and the like, unless specifically stated otherwise, or otherwise understood within the context as used, is generally intended to convey that certain embodiments include, while other embodiments do not include, certain features, elements and/or states. Thus, such conditional language is not generally intended to imply that features, elements and/or states are in any way required for one or more embodiments or that one or more embodiments necessarily include logic for deciding, with or without author input or prompting, whether these features, elements and/or states are included or are to be performed in any particular embodiment. The terms "comprising," "including," "having," and the like are synonymous and are used inclusively, in an open-ended fashion, and do not exclude additional elements, features, acts, operations, and so forth. Also, the term "or" is used in its inclusive sense (and not in its exclusive sense) so that when used, for example, to connect a list of elements, the term "or" means one, some, or all of the elements in the list. Further, the term "each," as used herein, in addition to having its ordinary meaning, can mean any subset of a set of elements to which the term "each" is applied.

While the above detailed description has shown, described, and pointed out novel features as applied to various embodiments, it will be understood that various omissions, substitutions, and changes in the form and details of the systems, devices or algorithms illustrated can be made without departing from the spirit of the disclosure. As will be recognized, certain embodiments of the disclosure described herein can be embodied within a form that does not provide all of the features and benefits set forth herein, as some features can be used or practiced separately from others.

The term "and/or" herein has its broadest, least limiting meaning which is the disclosure includes A alone, B alone, both A and B together, or A or B alternatively, but does not require both A and B or require one of A or one of B. As used herein, the phrase "at least one of" A, B, "and" C should be construed to mean a logical A or B or C, using a non-exclusive logical or.

The apparatuses and methods described herein may be implemented by one or more computer programs executed by one or more processors. The computer programs include processor-executable instructions that are stored on a non-transitory tangible computer readable medium. The computer programs may also include stored data. Non-limiting examples of the non-transitory tangible computer readable medium are nonvolatile memory, magnetic storage, and optical storage. Although the foregoing disclosure has been described in terms of certain preferred embodiments, other embodiments will be apparent to those of ordinary skill in the art from the disclosure herein. Additionally, other combinations, omissions, substitutions and modifications will be apparent to the skilled artisan in view of the disclosure herein. Accordingly, the present invention is not intended to be limited by the description of the preferred embodiments, but is to be defined by reference to claims.

Additionally, all publications, patents, and patent applications mentioned in this specification are herein incorporated by reference to the same extent as if each individual publication, patent, or patent application were specifically and individually indicated to be incorporated by reference.

What is claimed is:

1. A physiological measurement device comprising:

one or more emitters configured to emit light in an initial light pattern;

an optical transmission material configured to be positioned between the one or more emitters and a tissue measurement site, wherein the optical transmission material is configured to alter a direction of at least a portion of the light emitted from the one or more emitters to shape an output light pattern by which the emitted light is directed toward a surface of the tissue measurement site, wherein the output light pattern comprises a different geometric shape than the initial light pattern;

a plurality of detectors configured to detect at least a portion of the light after passing through tissue, the plurality of detectors further configured to output at least one signal responsive to the detected light;

a light block configured to prevent at least a portion of the light emitted from the one or more emitters from reaching the plurality of detectors without first reaching the tissue;

a surface comprising a dark-colored coating, the surface positioned between the plurality of detectors and the tissue, wherein an opening defined in the dark-colored coating is configured to allow at least a portion of light reflected from the tissue to pass through the surface; and

a processor configured to receive and process one or more signals responsive to the outputted at least one signal and determine a physiological parameter of a user responsive to the one or more signals.

2. The physiological measurement device of claim **1**, wherein the light block comprises an at least partially circular shape, and wherein the one or more emitters are positioned outside the light block and the plurality of detectors are positioned inside the light block.

3. The physiological measurement device of claim **1**, wherein the optical transmission material comprises glass.

4. The physiological measurement device of claim **1**, wherein the optical transmission material comprises plastic.

5. The physiological measurement device of claim **1**, wherein the plurality of detectors are arranged in an array having a spatial configuration corresponding to a shape of a portion of the tissue measurement site bounded by the light block.

6. The physiological measurement device of claim **1**, wherein the dark-colored coating comprises black pigment.

7. The physiological measurement device of claim **1**, wherein the device is configured to wirelessly transmit physiological parameter data to a separate device.

8. The physiological measurement device of claim **1**, further comprising a touch-screen display configured to present information related to the determined physiological parameter.

9. The physiological measurement device of claim **1**, wherein the output light pattern comprises a width and a length, and wherein the width is different than the length.

10. The physiological measurement device of claim **1**, wherein the output light pattern comprises an oval shape.

11. The physiological measurement device of claim **1**, wherein the physiological parameter is oxygen saturation.

12. The physiological measurement device of claim **1**, wherein the physiological parameter is pulse rate.

13. The physiological measurement device of claim **1**, wherein the opening defined in the dark-colored coating comprises a width and a length, and wherein the width is larger than the length.

14. A physiological measurement device comprising:

one or more optical sources configured to emit light of one or more wavelengths in an initial light pattern proximate a wrist of a user;

an optical transmission material configured to be positioned between the one or more optical sources and a tissue measurement site, wherein the optical transmission material is configured to alter a direction of at least a portion of the light emitted from the one or more optical sources to shape an output light pattern by which the emitted light is projected toward a surface of the tissue measurement site, the output light pattern comprising a different geometric shape than the initial light pattern;

a plurality of detectors configured to detect at least a portion of the light after passing through tissue, the plurality of detectors further configured to output at least one signal responsive to the detected light, wherein the one or more optical sources and the plurality of detectors are arranged in a reflectance measurement configuration;

a light block configured to prevent at least a portion of light emitted from the one or more optical sources from reaching the plurality of detectors without first reaching the tissue;

a surface comprising a dark-colored coating, the surface positioned between the plurality of detectors and the tissue, wherein an opening defined in the dark-colored coating is configured to allow at least a portion of light reflected from the tissue to pass through the surface;

a processor configured to receive and process one or more signals responsive to the outputted at least one signal and determine a physiological parameter of the user responsive to the one or more signals; and

a touch-screen display configured to present information responsive to the determined physiological parameter;

wherein the physiological measurement device is configured to wirelessly transmit physiological parameter data to a separate device.

15. The physiological measurement device of claim **14**, wherein the light block comprises an at least partially circular shape, and wherein the one or more optical sources are positioned outside the light block and the plurality of detectors are positioned inside the light block.

16. The physiological measurement device of claim **14**, wherein the optical transmission material comprises at least one of glass and plastic.

17. The physiological measurement device of claim **14**, wherein the output light pattern comprises a width and a length, and wherein the width is different than the length.

18. The physiological measurement device of claim **14**, wherein the physiological parameter is oxygen saturation.

19. The physiological measurement device of claim **14**, wherein the physiological parameter is pulse rate.

20. The physiological measurement device of claim **14**, wherein the opening defined in the dark-colored coating comprises a width and a length, and wherein the width is larger than the length.

21. The physiological measurement device of claim **14**, wherein the plurality of detectors are arranged in an array having a spatial configuration corresponding to a shape of a portion of the tissue measurement site bounded by the light block.

22. A physiological measurement device comprising:

one or more emitters configured to emit light;

a diffuser configured to be positioned between the one or more emitters and a tissue measurement site;

a circular shaped light block;

a plurality of detectors configured to detect at least a portion of the light after the light passes through a portion of the tissue measurement site bounded by the light block, wherein the plurality of detectors are arranged in an array having a spatial configuration corresponding to a shape of the portion of the tissue measurement site bounded by the circular shaped light block, wherein the plurality of detectors are further configured to output at least one signal responsive to the detected light;

wherein the light block is configured to prevent at least a portion of light emitted from the one or more emitters from reaching the plurality of detectors without first reaching tissue; and

a processor configured to receive and process one or more signals responsive to the outputted at least one signal and determine a physiological parameter of the user responsive to the one or more signals.

23. The physiological measurement device of claim **22**, wherein the one or more emitters are configured to emit the light in an initial light pattern, and wherein the diffuser comprises an optical transmission material configured to alter a direction of at least a portion of the light emitted from the one or more emitters to shape an output light pattern by which the emitted light is directed toward a surface of the tissue measurement site, and wherein the output light pattern comprises a different geometric shape than the initial light pattern.

24. The physiological measurement device of claim **22**, wherein the physiological parameter is oxygen saturation.

25. The physiological measurement device of claim **22**, wherein the physiological parameter is pulse rate.

* * * * *

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(54) **PHYSIOLOGICAL MONITORING DEVICES, SYSTEMS, AND METHODS**

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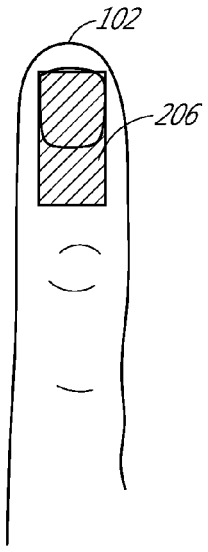
(57) **ABSTRACT**

A non-invasive, optical-based physiological monitoring system is disclosed. One embodiment includes an emitter configured to emit light. A diffuser is configured to receive and spread the emitted light, and to emit the spread light at a tissue measurement site. The system further includes a concentrator configured to receive the spread light after it has been attenuated by or reflected from the tissue measurement site. The concentrator is also configured to collect and concentrate the received light and to emit the concentrated light to a detector. The detector is configured to detect the concentrated light and to transmit a signal representative of the detected light. A processor is configured to receive the transmitted signal and to determine a physiological parameter, such as, for example, arterial oxygen saturation, in the tissue measurement site.

25 Claims, 7 Drawing Sheets



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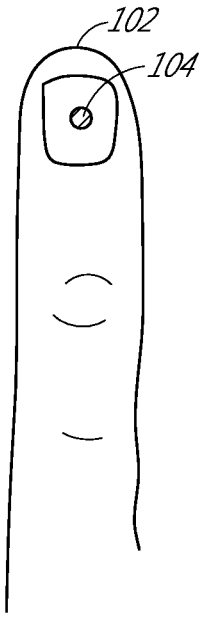

FIG. 1
(PRIOR ART)

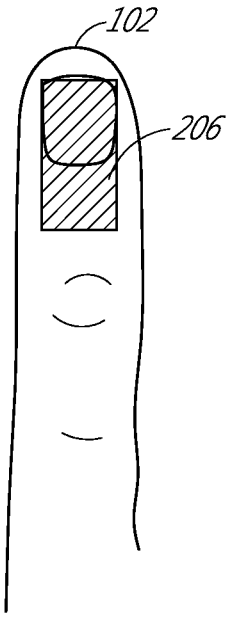

FIG. 2

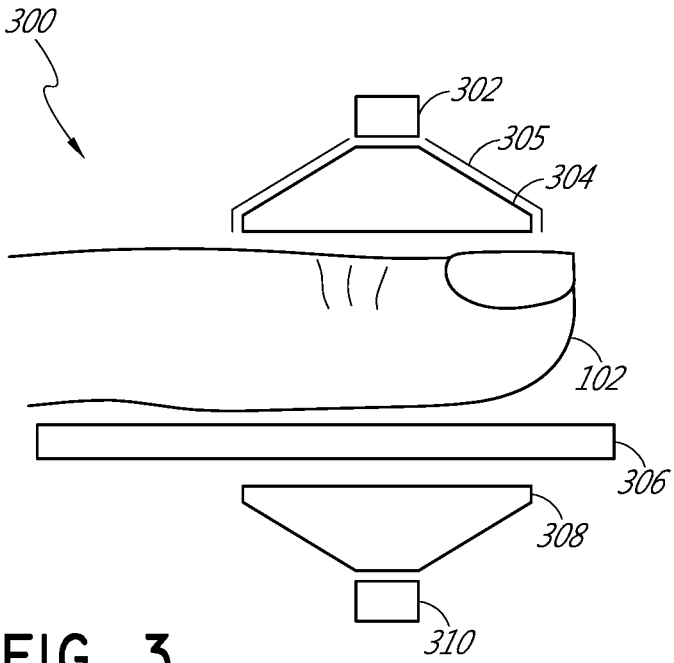

FIG. 3

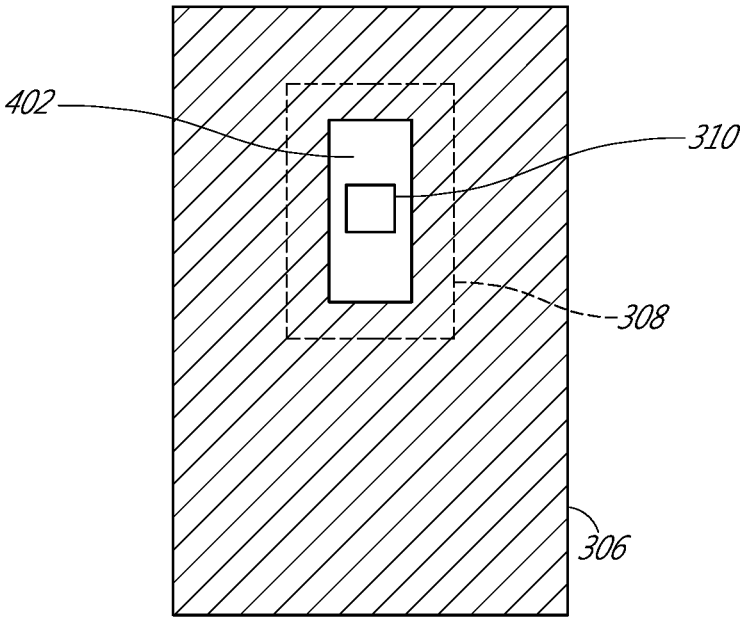

FIG. 4A

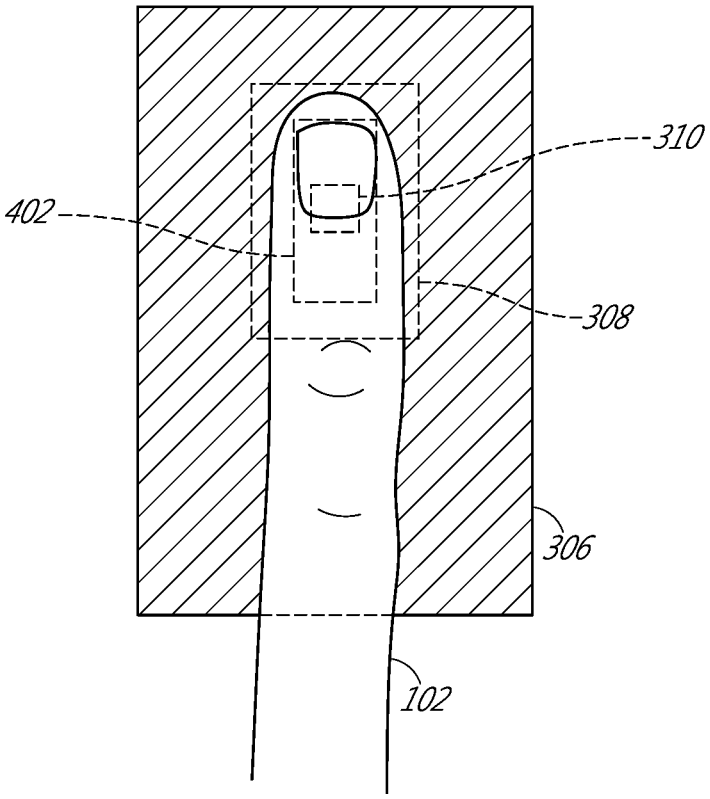

FIG. 4B

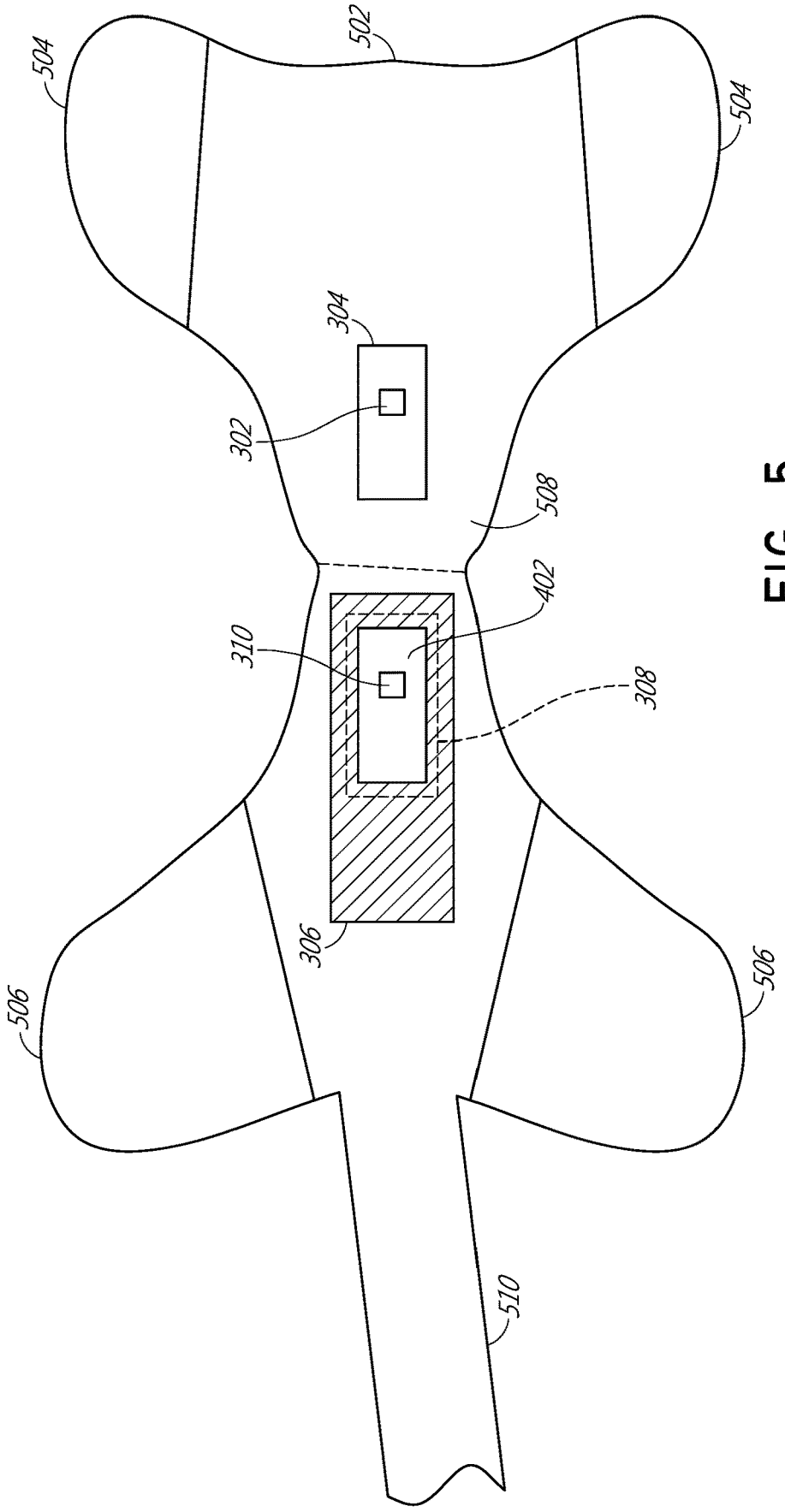

FIG. 5

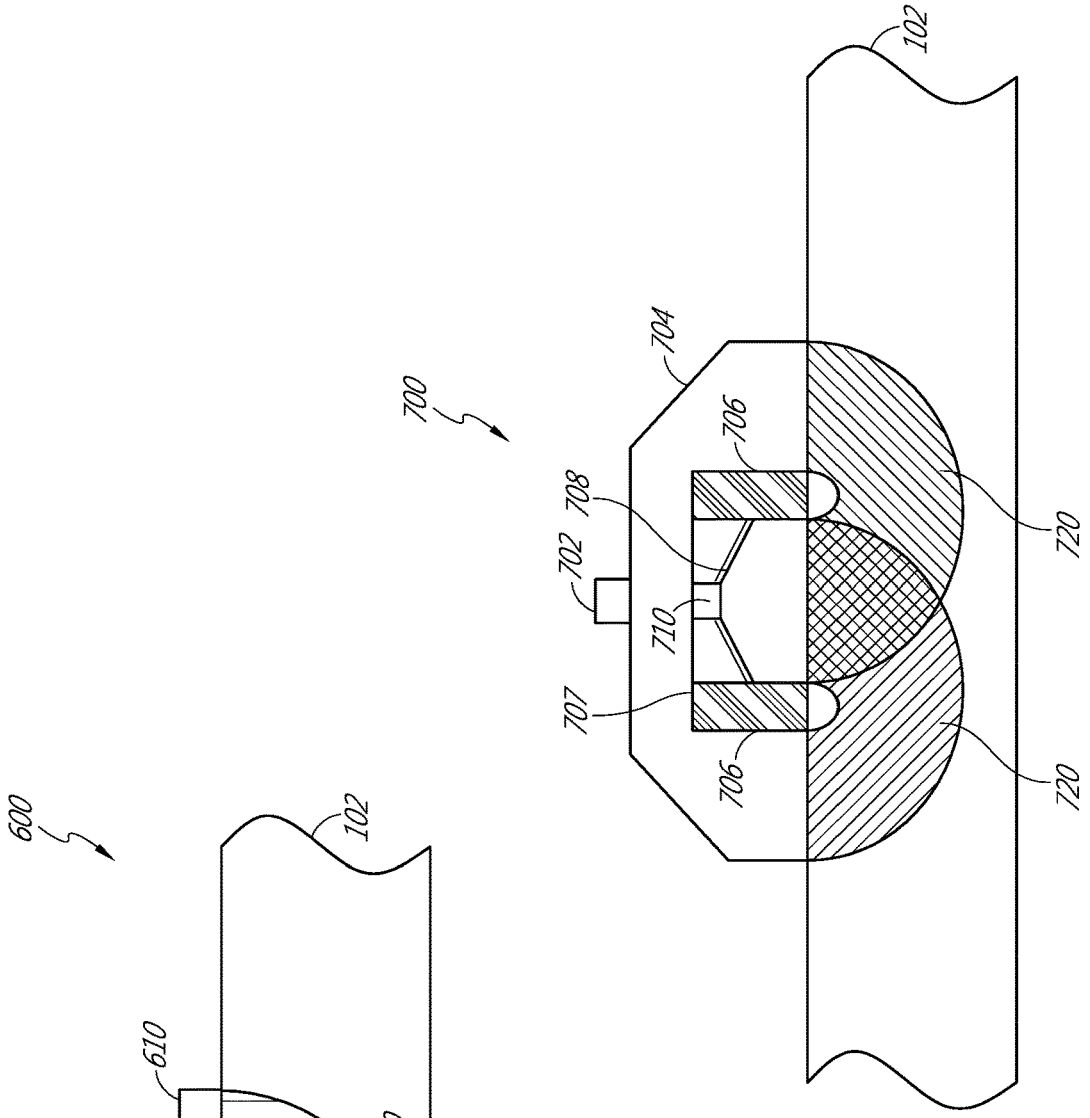

FIG. 7A

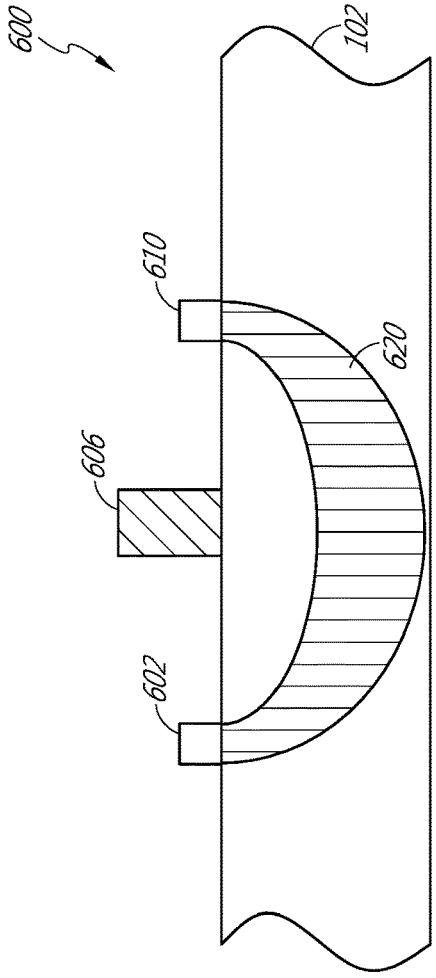

FIG. 6
(PRIOR ART)

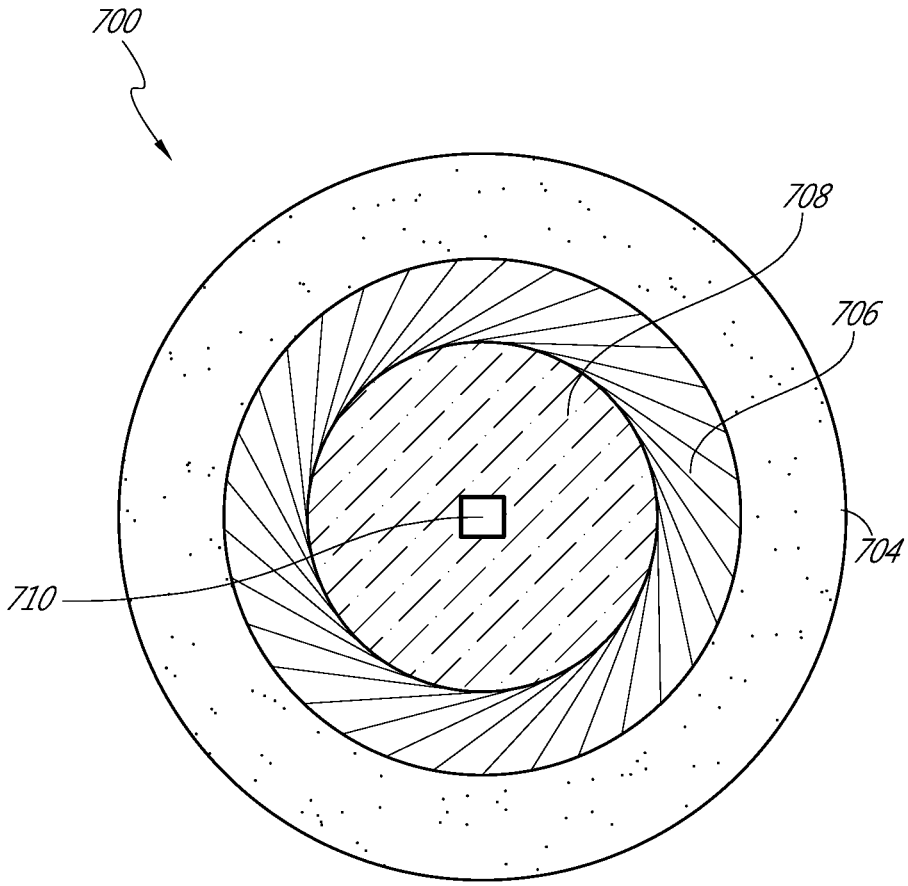

FIG. 7B

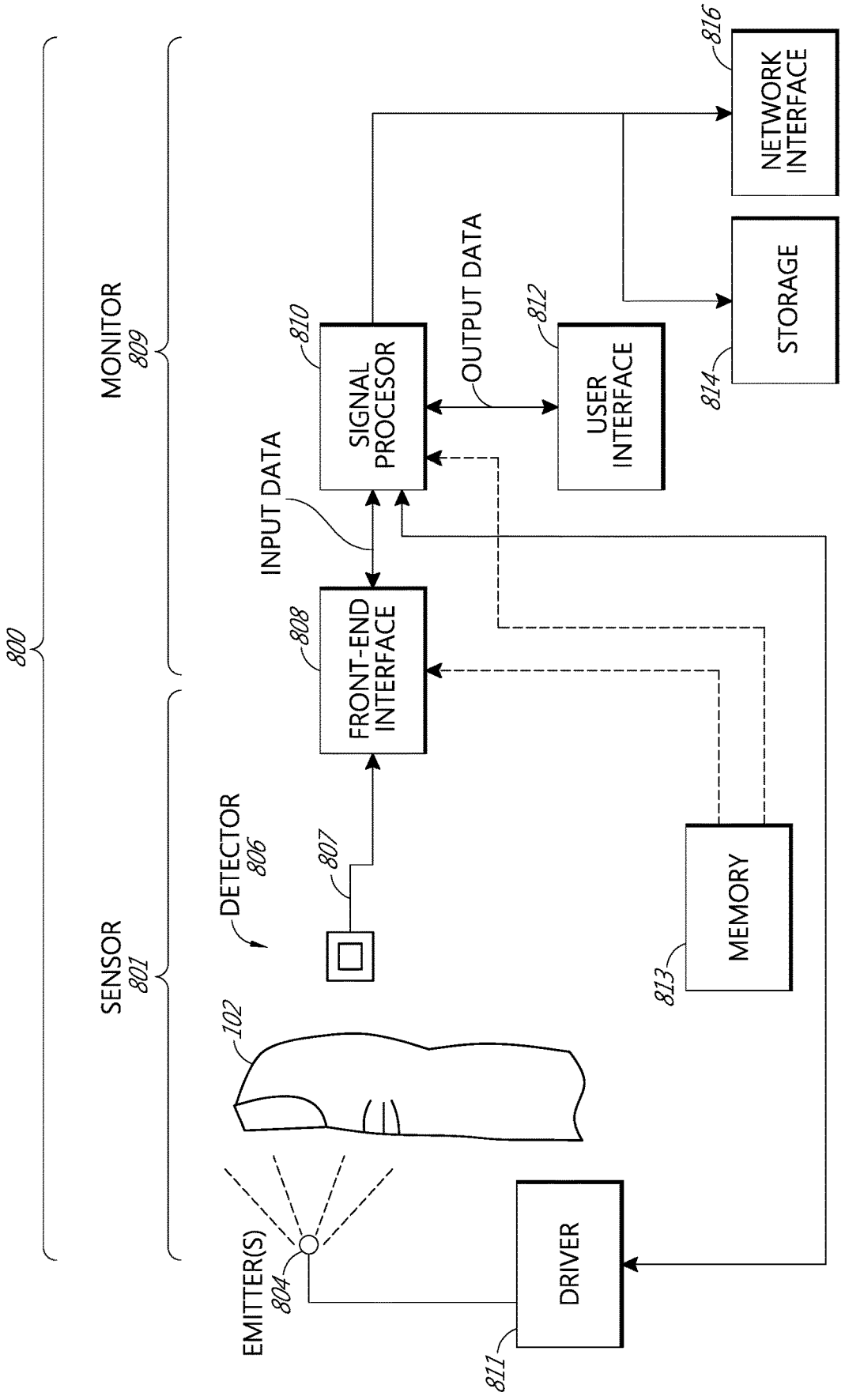
800
MONITOR
809
SENSOR
801
SIGNAL PROCESOR
810
OUTPUT DATA
USER INTERFACE
812
NETWORK INTERFACE
816
STORAGE
814
INPUT DATA
FRONT-END INTERFACE
808
DETECTOR
806
807
MEMORY
813
102
EMITTER(S)
804
DRIVER
811

FIG. 8

PHYSIOLOGICAL MONITORING DEVICES, SYSTEMS, AND METHODS

INCORPORATION BY REFERENCE TO ANY PRIORITY APPLICATIONS

The present application is a continuation of U.S. patent application Ser. No. 16/532,065 filed Aug. 5, 2019, which is a continuation of U.S. patent application Ser. No. 16/226,249 filed Dec. 19, 2018, which is a continuation of U.S. patent application Ser. No. 15/195,199 filed Jun. 28, 2016, which claims priority benefit under 35 U.S.C. § 119(e) from U.S. Provisional Application No. 62/188,430, filed Jul. 2, 2015, which is incorporated by reference herein. Any and all applications for which a foreign or domestic priority claim is identified in the Application Data Sheet as filed with the present application are hereby incorporated by reference under 37 CFR 1.57.

FIELD OF THE DISCLOSURE

The present disclosure relates to the field of non-invasive optical-based physiological monitoring sensors, and more particularly to systems, devices and methods for improving the non-invasive measurement accuracy of oxygen saturation, among other physiological parameters.

BACKGROUND

Spectroscopy is a common technique for measuring the concentration of organic and some inorganic constituents of a solution. The theoretical basis of this technique is the Beer-Lambert law, which states that the concentration C, of an absorbent in solution can be determined by the intensity of light transmitted through the solution, knowing the path-length d_λ, the intensity of the incident light $I_{0,\lambda}$, and the extinction coefficient $\varepsilon_{1,\lambda}$ at a particular wavelength A.

In generalized form, the Beer-Lambert law is expressed as:

$$I_\lambda = I_{0,\lambda} e^{-d_\lambda \cdot \mu_{a,\lambda}} \quad (1)$$

$$\mu_{a,\lambda} = \sum_{i=1}^{n} \varepsilon_{i,\lambda} \cdot c_i \quad (2)$$

where $\mu_{\alpha,\lambda}$ is the bulk absorption coefficient and represents the probability of absorption per unit length. The minimum number of discrete wavelengths that are required to solve equations 1 and 2 is the number of significant absorbers that are present in the solution.

A practical application of this technique is pulse oximetry, which utilizes a noninvasive sensor to measure oxygen saturation and pulse rate, among other physiological parameters. Pulse oximetry relies on a sensor attached externally to the patient to output signals indicative of various physiological parameters, such as a patient's blood constituents and/or analytes, including for example a percent value for arterial oxygen saturation, among other physiological parameters. The sensor has an emitter that transmits optical radiation of one or more wavelengths into a tissue site and a detector that responds to the intensity of the optical radiation after absorption by pulsatile arterial blood flowing within the tissue site. Based upon this response, a processor determines the relative concentrations of oxygenated hemoglobin (HbO_2) and deoxygenated hemoglobin (Hb) in the blood so as to derive oxygen saturation, which can provide early detection of potentially hazardous decreases in a patient's oxygen supply.

A pulse oximetry system generally includes a patient monitor, a communications medium such as a cable, and/or a physiological sensor having one or more light emitters and a detector, such as one or more light-emitting diodes (LEDs) and a photodetector. The sensor is attached to a tissue site, such as a finger, toe, earlobe, nose, hand, foot, or other site having pulsatile blood flow which can be penetrated by light from the one or more emitters. The detector is responsive to the emitted light after attenuation or reflection by pulsatile blood flowing in the tissue site. The detector outputs a detector signal to the monitor over the communication medium. The monitor processes the signal to provide a numerical readout of physiological parameters such as oxygen saturation (SpO2) and/or pulse rate. A pulse oximetry sensor is described in U.S. Pat. No. 6,088,607 entitled Low Noise Optical Probe; pulse oximetry signal processing is described in U.S. Pat. Nos. 6,650,917 and 6,699,194 entitled Signal Processing Apparatus and Signal Processing Apparatus and Method, respectively; a pulse oximeter monitor is described in U.S. Pat. No. 6,584,336 entitled Universal/Upgrading Pulse Oximeter; all of which are assigned to Masimo Corporation, Irvine, Calif., and each is incorporated by reference herein in its entirety.

There are many sources of measurement error introduced to pulse oximetry systems. Some such sources of error include the pulse oximetry system's electronic components, including emitters and detectors, as well as chemical and structural physiological differences between patients. Another source of measurement error is the effect of multiple scattering of photons as the photons pass through the patient's tissue (arterial blood) and arrive at the sensor's light detector.

SUMMARY

This disclosure describes embodiments of non-invasive methods, devices, and systems for measuring blood constituents, analytes, and/or substances such as, by way of non-limiting example, oxygen, carboxyhemoglobin, methemoglobin, total hemoglobin, glucose, proteins, lipids, a percentage thereof (e.g., saturation), pulse rate, perfusion index, oxygen content, total hemoglobin, Oxygen Reserve Index™ (ORI™) or for measuring many other physiologically relevant patient characteristics. These characteristics can relate to, for example, pulse rate, hydration, trending information and analysis, and the like.

In an embodiment, an optical physiological measurement system includes an emitter configured to emit light of one or more wavelengths. The system also includes a diffuser configured to receive the emitted light, to spread the received light, and to emit the spread light over a larger tissue area than would otherwise be penetrated by the emitter directly emitting light at a tissue measurement site. The tissue measurement site can include, such as, for example, a finger, a wrist, or the like. The system further includes a concentrator configured to receive the spread light after it has been attenuated by or reflected from the tissue measurement site. The concentrator is also configured to collect and concentrate the received light and to emit the concentrated light to a detector. The detector is configured to detect the concentrated light and to transmit a signal indicative of the detected light. The system also includes a processor configured to receive the transmitted signal indicative of the detected light and to determine, based on an

amount of absorption, an analyte of interest, such as, for example, arterial oxygen saturation or other parameter, in the tissue measurement site.

In certain embodiments of the present disclosure, the diffuser comprises glass, ground glass, glass beads, opal glass, or a microlens-based, band-limited, engineered diffuser that can deliver efficient and uniform illumination. In some embodiments the diffuser is further configured to define a surface area shape by which the emitted spread light is distributed onto a surface of the tissue measurement site. The defined surface area shape can include, by way of non-limiting example, a shape that is substantially rectangular, square, circular, oval, or annular, among others.

According to some embodiments, the optical physiological measurement system includes an optical filter having a light-absorbing surface that faces the tissue measurement site. The optical filter also has an opening that is configured to allow the spread light, after being attenuated by the tissue measurement site, to be received by the concentrator. In an embodiment, the opening has dimensions, wherein the dimensions of the opening are similar to the defined surface area shape by which the emitted spread light is distributed onto the surface of the tissue measurement site. In an embodiment, the opening has dimensions that are larger than the defined surface area shape by which the emitted spread light is distributed onto the surface of the tissue measurement site. In other embodiments, the dimensions of the opening in the optical filter are not the same as the diffuser opening, but the dimensions are larger than the detector package.

In other embodiments of the present disclosure, the concentrator comprises glass, ground glass, glass beads, opal glass, or a compound parabolic concentrator. In some embodiments the concentrator comprises a cylindrical structure having a truncated circular conical structure on top. The truncated section is adjacent the detector. The light concentrator is structured to receive the emitted optical radiation, after reflection by the tissue measurement site, and to direct the reflected light to the detector.

In accordance with certain embodiments of the present disclosure, the processor is configured to determine an average level of the light detected by the detector. The average level of light is used to determine a physiological parameter in the tissue measurement site.

According to another embodiment, a method to determine a constituent or analyte in a patient's blood is disclosed. The method includes emitting, from an emitter, light of at least one wavelength; spreading, with a diffuser, the emitted light and emitting the spread light from the diffuser to a tissue measurement site; receiving, by a concentrator, the spread light after the spread light has been attenuated by the tissue measurement site; concentrating, by the concentrator, the received light and emitting the concentrated light from the concentrator to a detector; detecting, with the detector, the emitted concentrated light; transmitting, from the detector, a signal responsive to the detected light; receiving, by a processor, the transmitted signal responsive to the detected light; and processing, by the processor, the received signal responsive to the detected light to determine a physiological parameter.

In some embodiments, the method to determine a constituent or analyte in a patient's blood includes filtering, with a light-absorbing detector filter, scattered portions of the emitted spread light. According to an embodiment, the light-absorbing detector filter is substantially rectangular in shape and has outer dimensions in the range of approximately 1-5 cm in width and approximately 2-8 cm in length, and has an opening through which emitted light may pass, the opening having dimensions in the range of approximately 0.25-3 cm in width and approximately 1-7 cm in length. In another embodiment, the light-absorbing detector filter is substantially square in shape and has outer dimensions in the range of approximately 0.25-10 cm^2, and has an opening through which emitted light may pass, the opening having dimensions in the range of approximately 0.1-8 cm^2. In yet another embodiment, the light-absorbing detector filter is substantially rectangular in shape and has outer dimensions of approximately 3 cm in width and approximately 6 cm in length, and has an opening through which emitted light may pass, the opening having dimensions of approximately 1.5 cm in width and approximately 4 cm in length.

In still other embodiments of the method to determine a constituent or analyte in a patient's blood, spreading, with a diffuser, the emitted light and emitting the spread light from the diffuser to a tissue measurement site is performed by at least one of a glass diffuser, a ground glass diffuser, a glass bead diffuser, an opal glass diffuser, and an engineered diffuser. In some embodiments the emitted spread light is emitted with a substantially uniform intensity profile. And in some embodiments, emitting the spread light from the diffuser to the tissue measurement site includes spreading the emitted light so as to define a surface area shape by which the emitted spread light is distributed onto a surface of the tissue measurement site.

According to yet another embodiment, a pulse oximeter is disclosed. The pulse oximeter includes an emitter configured to emit light at one or more wavelengths. The pulse oximeter also includes a diffuser configured to receive the emitted light, to spread the received light, and to emit the spread light directed at a tissue measurement sight. The pulse oximeter also includes a detector configured to detect the emitted spread light after being attenuated by or reflected from the tissue measurement site and to transmit a signal indicative of the detected light. The pulse oximeter also includes a processor configured to receive the transmitted signal and to process the received signal to determine an average absorbance of a blood constituent or analyte in the tissue measurement site over a larger measurement site area than can be performed with a point light source or point detector. In some embodiments, the diffuser is further configured to define a surface area shape by which the emitted spread light is distributed onto a surface of the tissue measurement site, and the detector is further configured to have a detection area corresponding to the defined surface area shape by which the emitted spread light is distributed onto the surface of the tissue measurement site. According to some embodiments, the detector comprises an array of detectors configured to cover the detection area. In still other embodiments, the processor is further configured to determine an average of the detected light.

For purposes of summarizing, certain aspects, advantages and novel features of the disclosure have been described herein. It is to be understood that not necessarily all such advantages can be achieved in accordance with any particular embodiment of the systems, devices and/or methods disclosed herein. Thus, the subject matter of the disclosure herein can be embodied or carried out in a manner that achieves or optimizes one advantage or group of advantages as taught herein without necessarily achieving other advantages as can be taught or suggested herein.

BRIEF DESCRIPTION OF THE DRAWINGS

Throughout the drawings, reference numbers can be reused to indicate correspondence between referenced ele-

ments. The drawings are provided to illustrate embodiments of the disclosure described herein and not to limit the scope thereof.

FIG. **1** illustrates a conventional approach to two-dimensional pulse oximetry in which the emitter is configured to emit optical radiation as a point optical source.

FIG. **2** illustrates the disclosed three-dimensional approach to pulse oximetry in which the emitted light irradiates a substantially larger volume of tissue as compared to the point source approach described with respect to FIG. **1**.

FIG. **3** illustrates schematically a side view of a three-dimensional pulse oximetry sensor according to an embodiment of the present disclosure.

FIG. **4**A is a top view of a portion of a three-dimensional pulse oximetry sensor according to an embodiment of the present disclosure.

FIG. **4**B illustrates the top view of a portion of the three-dimensional pulse oximetry sensor shown in FIG. **4**A, with the addition of a tissue measurement site in operational position.

FIG. **5** illustrates a top view of a three-dimensional pulse oximetry sensor according to an embodiment of the present disclosure.

FIG. **6** illustrates a conventional two-dimensional approach to reflective pulse oximetry in which the emitter is configured to emit optical radiation as a point optical source.

FIG. **7**A is a simplified schematic side view illustration of a reflective three-dimensional pulse oximetry sensor according to an embodiment of the present disclosure.

FIG. **7**B is a simplified schematic top view illustration of the three-dimensional reflective pulse oximetry sensor of FIG. **7**A.

FIG. **8** illustrates a block diagram of an example pulse oximetry system capable of noninvasively measuring one or more blood analytes in a monitored patient, according to an embodiment of the disclosure.

DETAILED DESCRIPTION

FIG. **1** illustrates schematically a conventional pulse oximetry sensor having a two-dimensional (2D) approach to pulse oximetry. As illustrated, the emitter **104** is configured to emit optical radiation as a point optical source, i.e., an optical radiation source that has negligible dimensions such that it may be considered as a point. This approach is referred to herein as "two-dimensional" pulse oximetry because it applies a two-dimensional analytical model to the three-dimensional space of the tissue measurement site **102** of the patient. Point optical sources feature a defined, freely selectable, and homogeneous light beam area. Light beams emitted from LED point sources often exhibit a strong focus which can produce a usually sharply-defined and evenly-lit illuminated spot often with high intensity dynamics. Illustratively, when looking at the surface of the tissue measurement site **102** (or "sample tissue"), which in this example is a finger, a small point-like surface area of tissue **204** is irradiated by a point optical source. In some embodiments, the irradiated circular area of the point optical source is in the range between 8 and 150 microns. Illustratively, the emitted point optical source of light enters the tissue measurement site **102** as a point of light. As the light penetrates the depth of the tissue **102**, it does so as a line or vector, representing a two-dimensional construct within a three-dimensional structure, namely the patient's tissue **102**.

Use of a point optical source is believed to reduce variability in light pathlength which would lead to more accurate oximetry measurements. However, in practice, photons do not travel in straight paths. Instead, the light particles scatter, bouncing around between various irregular objects (such as, for example, red blood cells) in the patient's blood. Accordingly, photon pathlengths vary depending on, among other things, their particular journeys through and around the tissue at the measurement site **102**. This phenomenon is referred to as "multiple scattering." In a study, the effects of multiple scattering were examined by comparing the results of photon diffusion analysis with those obtained using an analysis based on the Beer-Lambert law, which neglects multiple scattering in the determination of light pathlength. The study found that that the difference between the average lengths of the paths traveled by red and infrared photons makes the oximeter's calibration curve (based on measurements obtained from normal subjects) sensitive to the total attenuation coefficients of the tissue in the two wavelength bands used for pulse oximetry, as well as to absorption by the pulsating arterial blood.

FIG. **2** illustrates schematically the disclosed systems, devices, and methods to implement three-dimensional (3D) pulse oximetry in which the emitted light irradiates a larger volume of tissue at the measurement site **102** as compared to the 2D point optical source approach described with respect to FIG. **1**. In an embodiment, again looking at the surface of the tissue measurement site **102**, the irradiated surface area **206** of the measurement site **102** is substantially rectangular in shape with dimensions in the range of approximately 0.25-3 cm in width and approximately 1-6 cm in length. In another embodiment, the irradiated surface area **206** of the measurement site **102** is substantially rectangular in shape and has dimensions of approximately 1.5 cm in width and approximately 2 cm in length. In another embodiment, the irradiated surface area **206** of the measurement site **102** is substantially rectangular in shape and has dimensions of approximately 0.5 cm in width and approximately 1 cm in length. In another embodiment, the irradiated surface area **206** of the measurement site **102** is substantially rectangular in shape has dimensions of approximately 1 cm in width and approximately 1.5 cm in length. In yet another embodiment, the irradiated surface area **206** of the measurement site **102** is substantially square in shape and has dimensions in a range of approximately 0.25-9 cm^2. In certain embodiments, the irradiated surface area **206** of the measurement site **102** is within a range of approximately 0.5-2 cm in width, and approximately 1-4 cm in length. Of course a skilled artisan will appreciate that many other shapes and dimensions of irradiated surface area **206** can be used. Advantageously, by irradiating the tissue measurement site **102** with a surface area **206**, the presently disclosed systems, devices, and methods apply a three-dimensional analytical model to the three-dimensional structure being measured, namely, the patient's sample tissue **102**.

According to the Beer-Lambert law, the amount of light absorbed by a substance is proportional to the concentration of the light-absorbing substance in the irradiated solution (i.e., arterial blood). Advantageously, by irradiating a larger volume of tissue **102**, a larger sample size of light attenuated (or reflected) by the tissue **102** is measured. The larger, 3D sample provides a data set that is more representative of the complete interaction of the emitted light as it passes through the patient's blood as compared to the 2D point source approach described above with respect to FIG. **1**. By taking an average of the detected light, as detected over a surface area substantially larger than a single point, the disclosed pulse oximetry systems, devices, and methods will yield a

more accurate measurement of the emitted light absorbed by the tissue, which will lead to a more accurate oxygen saturation measurement.

FIG. **3** illustrates schematically a side view of a pulse oximetry 3D sensor **300** according to an embodiment of the present disclosure. In the illustrated embodiment, the 3D sensor **300** irradiates the tissue measurement site **102** and detects the emitted light, after being attenuated by the tissue measurement site **102**. In other embodiments, for example, as describe below with respect to FIGS. **7**A and **7**B, the 3D sensor **300** can be arranged to detect light that is reflected by the tissue measurement site **102**. The 3D sensor **300** includes an emitter **302**, a light diffuser **304**, a light-absorbing detector filter **306**, a light concentrator **308**, and a detector **310**. In some optional embodiments, the 3D sensor **300** further includes a reflector **305**. The reflector **305** can be a metallic reflector or other type of reflector. Reflector **305** can be a coating, film, layer or other type of reflector. The reflector **305** can serve as a reflector to prevent emitted light from emitting out of a top portion of the light diffuser **304** such that light from the emitter **302** is directed in the tissue rather than escaping out of a side or top of the light diffuser **304**. Additionally, the reflector **305** can prevent ambient light from entering the diffuser **304** which might ultimately cause errors within the detected light. The reflector **305** also prevent light piping that might occur if light from the detector **302** is able to escape from the light diffuser **304** and be pipped around a sensor securement mechanism to detector **310** without passing through the patient's tissue **102**.

The emitter **302** can serve as the source of optical radiation transmitted towards the tissue measurement site **102**. The emitter **302** can include one or more sources of optical radiation, such as LEDs, laser diodes, incandescent bulbs with appropriate frequency-selective filters, combinations of the same, or the like. In an embodiment, the emitter **302** includes sets of optical sources that are capable of emitting visible and near-infrared optical radiation. In some embodiments, the emitter **302** transmits optical radiation of red and infrared wavelengths, at approximately 650 nm and approximately 940 nm, respectively. In some embodiments, the emitter **302** includes a single source optical radiation.

The light diffuser **304** receives the optical radiation emitted from the emitter **302** and spreads the optical radiation over an area, such as the area **206** depicted in FIG. **2**. In some embodiments, the light diffuser **304** is a beam shaper that can homogenize the input light beam from the emitter **302**, shape the output intensity profile of the received light, and define the way (e.g., the shape or pattern) the emitted light is distributed to the tissue measurement site **102**. Examples of materials that can be used to realize the light diffuser **304** include, without limitation, a white surface, glass, ground glass, glass beads, polytetrafluoroethylene (also known as Teflon®, opal glass, and greyed glass, to name a few. Additionally, engineered diffusers can be used to realize the diffuser **304** by providing customized light shaping with respect to intensity and distribution. Such diffusers can, for example, deliver substantially uniform illumination over a specified target area (such as, for example, irradiated surface area **206**) in an energy-efficient manner. Examples of engineered diffusers can include molded plastics with specific shapes, patterns or textures designed to diffuse the emitter light across the entirety of the patient's tissue surface.

Advantageously, the diffuser **304** can receive emitted light in the form of a point optical source and spread the light to fit a desired surface area on a plane defined by the surface of the tissue measurement site **102**. In an embodiment, the diffuser **304** is made of ground glass which spreads the emitted light with a Gausian intensity profile. In another embodiment the diffuser **304** includes glass beads. In some embodiments, the diffuser **304** is constructed so as to diffuse the emitted light in a Lambertian pattern. A Lambertian pattern is one in which the radiation intensity is substantially constant throughout the area of dispersion. One such diffuser **304** is made from opal glass. Opal glass is similar to ground glass, but has one surface coated with a milky white coating to diffuse light evenly. In an embodiment, the diffuser **304** is capable of distributing the emitted light on the surface of a plane (e.g., the surface of the tissue measurement site **102**) in a predefined geometry (e.g., a rectangle, square, or circle), and with a substantially uniform intensity profile and energy distribution. In some embodiments, the efficiency, or the amount of light transmitted by the diffuser **304**, is greater than 70% of the light emitted by the emitter **302**. In some embodiments, the efficiency is greater than 90% of the emitted light. Other optical elements known in the art may be used for the diffuser **304**.

In an embodiment, the diffuser **304** has a substantially rectangular shape having dimensions within a range of approximately 0.5-2 cm in width and approximately 1-4 centimeters in length. In another embodiment, the substantially rectangular shape of the diffuser **304** has dimensions of approximately 0.5 cm in width and approximately 1 cm in length. In another embodiment, the diffuser's **304** substantially rectangular shape has dimensions of approximately 1 cm in width and approximately 1.5 cm in length. In yet another embodiment, the diffuser **304** has a substantially square shape with dimensions in the range of approximately 0.25-10 cm^2.

The light-absorbing detector filter **306**, which is also depicted in FIG. **4**A in a top view, is a planar surface having an opening **402** through which the emitted light may pass after being attenuated by the tissue measurement site **102**. In the depicted embodiment, the opening **402** is rectangular-shaped, with dimensions substantially similar to the irradiated surface area **206**. According to an embodiment, the light-absorbing detector filter is substantially rectangular in shape and has outer dimensions of 4 cm in width and 8 cm in length, and has an opening through which emitted light may pass, the opening having dimensions of 2 cm in width and 5 cm in length. In another embodiment, the light-absorbing detector filter is substantially rectangular in shape and has outer dimensions in the range of 1-3 cm in width and 2-8 cm in length, and has an opening through which emitted light may pass, the opening having dimensions in the range of 0.25-2 cm in width and 1-4 cm in length. In yet another embodiment, the light-absorbing detector filter is substantially rectangular in shape and has outer dimensions of 3 cm in width and 6 cm in length, and has an opening through which emitted light may pass, the opening having dimensions of 1.5 cm in width and 4 cm in length.

The top surface of the light-absorbing filter **306** (facing the tissue measurement site **102** and the emitter **302**) is coated with a material that absorbs light, such as, for example, black pigment. Many other types of light-absorbing materials are well known in the art and can be used with the detector filter **306**. During operation, light emitted from the emitter **302** can reflect off of the tissue measurement site **102** (or other structures within the 3D sensor **300**) to neighboring portions of the 3D sensor **300**. If those neighboring portions of the 3D sensor **300** possess reflective surfaces, then the light can reflect back to the tissue measurement site **102**, progress through the tissue and arrive at the detector **310**. Such multiple scattering can result in detecting photons whose pathlengths are considerably lon-

ger than most of the light that is detected, thereby introducing variations in pathlength which will affect the accuracy of the measurements of the pulse oximetry 3D sensor **300**. Advantageously, the light-absorbing filter **306** reduces or eliminates the amount of emitted light that is reflected in this manner because it absorbs such reflected light, thereby stopping the chain of scattering events. In certain embodiments, the sensor-facing surfaces of other portions of the 3D sensor **300** are covered in light-absorbing material to further decrease the effect of reflective multiple scattering.

The light concentrator **308** is a structure to receive the emitted optical radiation, after attenuation by the tissue measurement site **102**, to collect and concentrate the dispersed optical radiation, and to direct the collected and concentrated optical radiation to the detector **310**. In an embodiment, the light concentrator **308** is made of ground glass or glass beads. In some embodiments, the light concentrator **308** includes a compound parabolic concentrator.

As described above with respect to FIG. **1**, the detector **310** captures and measures light from the tissue measurement site **102**. For example, the detector **310** can capture and measure light transmitted from the emitter **302** that has been attenuated by the tissue in the measurement site **102**. The detector **310** can output a detector signal responsive to the light captured or measured. The detector **310** can be implemented using one or more photodiodes, phototransistors, or the like. In addition, a plurality of detectors **310** can be arranged in an array with a spatial configuration corresponding to the irradiated surface area **206** to capture the attenuated or reflected light from the tissue measurement site.

Referring to FIG. **4**A, a top view of a portion of the 3D sensor **300** is provided. The light-absorbing detector filter **306** is illustrated having a top surface coated with a light-absorbing material. The light-absorbing material can be a black opaque material or coating or any other dark color or coating configured to absorb light. Additionally, a rectangular opening **402** is positioned relative to the light concentrator **308** (shown in phantom) and the detector **310** such that light may pass through the rectangular opening **402**, into the light concentrator **308**, and to the detector **310**. FIG. **4**B illustrates the top view of a portion of the 3D sensor **300** as in FIG. **4**A, with the addition of the tissue measurement site **102** in operational position. Accordingly, the rectangular opening **402**, the light concentrator **308** and the detector **310** are shown in phantom as being under the tissue measurement site **102**. In FIGS. **4**A and **4**B, the light concentrator **308** is shown to have dimensions significantly larger than the dimensions of the rectangular opening **402**. In other embodiments, the dimensions of the light concentrator **308**, the rectangular opening **402**, and the irradiated surface area **206** are substantially similar.

FIG. **5** illustrates a top view of a 3D pulse oximetry sensor **500** according to an embodiment of the present disclosure. The 3D sensor **500** is configured to be worn on a patient's finger **102**. The 3D sensor **500** includes an adhesive substrate **502** having front flaps **504** and rear flaps **506** extending outward from a center portion **508** of the 3D sensor **500**. The center portion **508** includes components of the 3D pulse oximetry sensor **300** described with respect to FIGS. **3**, **4**A and **4**B. On the front side of the adhesive substrate **502** the emitter **302** and the light diffuser **304** are positioned. On the rear side of the adhesive substrate **502** the light-absorbent detector filter **306**, the light concentrator **308** and the detector **310** are positioned. In use, the patient's finger serving as the tissue measurement site **102** is positioned over the rectangular opening **402** such that when the front portion of the adhesive substrate is folded over on top of the patient's finger **102**, the emitter **302** and the light diffuser **304** are aligned with the measurement site **102**, the filter **306**, the light concentrator **308** and the detector **310**. Once alignment is established, the front and rear flaps **504**, **506** can be wrapped around the finger measurement site **102** such that the adhesive substrate **502** provides a secure contact between the patient's skin and the 3D sensor **500**. FIG. **5** also illustrates an example of a sensor connector cable **510** which is used to connect the 3D sensor **500** to a monitor **809**, as described with respect to FIG. **8**.

FIG. **6** is a simplified schematic illustration of a conventional, 2D approach to reflective pulse oximetry in which the emitter is configured to emit optical radiation as a point optical source. Reflective pulse oximetry is a method by which the emitter and detector are located on the same side of the tissue measurement site **102**. Light is emitted into a tissue measurement site **102** and attenuated. The emitted light passes into the tissue **102** and is then reflected back to the same side of the tissue measurement site **102** as the emitter. As illustrated in FIG. **6**, a depicted reflective 2D pulse oximetry sensor **600** includes an emitter **602**, a light block **606**, and a detector **610**. The light block **606** is necessary because the emitter **602** and the detector **610** are located on the same side of the tissue measurement site **102**. Accordingly, the light block **606** prevents incident emitter light, which did not enter the tissue measurement site **102**, from arriving at the detector **610**. The depicted 2D pulse oximetry sensor **600** is configured to emit light as a point source. As depicted in FIG. **6**, a simplified illustration of the light path **620** of the emitted light from the emitter **602**, through the tissue measurement site **102**, and to the detector **610** is provided. Notably, a point source of light is emitted, and a point source of light is detected. As discussed above with respect to FIG. **1**, use of a point optical source can result in substantial measurement error due to pathlength variability resulting from the multiple scatter phenomenon. The sample space provided by a 2D point optical emitter source is not large enough to account for pathlength variability, which will skew measurement results.

FIGS. **7**A and **7**B are simplified schematic side and top views, respectively, of a 3D reflective pulse oximetry sensor **700** according to an embodiment of the present disclosure. In the illustrated embodiment, the 3D sensor **700** irradiates the tissue measurement site **102** and detects the emitted light that is reflected by the tissue measurement site **102**. The 3D sensor **700** can be placed on a portion of the patient's body that has relatively flat surface, such as, for example a wrist, because the emitter **702** and detector **710** are on located the same side of the tissue measurement site **102**. The 3D sensor **700** includes an emitter **702**, a light diffuser **704**, a light block **706**, a light concentrator **708**, and a detector **710**.

As previously described, the emitter **702** can serve as the source of optical radiation transmitted towards the tissue measurement site **102**. The emitter **702** can include one or more sources of optical radiation. Such sources of optical radiation can include LEDs, laser diodes, incandescent bulbs with appropriate frequency-selective filters, combinations of the same, or the like. In an embodiment, the emitter **702** includes sets of optical sources that are capable of emitting visible and near-infrared optical radiation. In some embodiments, the emitter **702** transmits optical radiation of red and infrared wavelengths, at approximately 650 nm and approximately 940 nm, respectively. In some embodiments, the emitter **702** includes a single source of optical radiation.

The light diffuser **704** receives the optical radiation emitted from the emitter **702** and homogenously spreads the optical radiation over a wide, donut-shaped area, such as the

area outlined by the light diffuser **704** as depicted in FIG. **7**B. Advantageously, the diffuser **704** can receive emitted light in the form of a 2D point optical source (or any other form) and spread the light to fit the desired surface area on a plane defined by the surface of the tissue measurement site **102**. In an embodiment, the diffuser **704** is made of ground glass or glass beads. A skilled artisan will understand that may other materials can be used to make the light diffuser **704**.

The light blocker **706** includes an annular ring having a cover portion **707** sized and shaped to form a light isolation chamber for the light concentrator **708** and the detector **710**. (For purposes of illustration, the light block cover **707** is not illustrated in FIG. **7**B.) The light blocker **706** and the cover **707** can be made of any material that optically isolates the light concentrator **708** and the detector **710**. The light isolation chamber formed by the light blocker **706** and cover **707** ensures that the only light detected by the detector **710** is light that is reflected from the tissue measurement site.

The light concentrator **708** is a cylindrical structure with a truncated circular conical structure on top, the truncated section of which of which is adjacent the detector **710**. The light concentrator **708** is structured to receive the emitted optical radiation, after reflection by the tissue measurement site **102**, and to direct the reflected light to the detector **710**. In an embodiment, the light concentrator **708** is made of ground glass or glass beads. In some embodiments, the light concentrator **708** includes a compound parabolic concentrator.

As previously described, the detector **710** captures and measures light from the tissue measurement site **102**. For example, the detector **710** can capture and measure light transmitted from the emitter **702** that has been reflected from the tissue in the measurement site **102**. The detector **710** can output a detector signal responsive to the light captured or measured. The detector **710** can be implemented using one or more photodiodes, phototransistors, or the like. In addition, a plurality of detectors **710** can be arranged in an array with a spatial configuration corresponding to the irradiated surface area depicted in FIG. **7**B by the light concentrator **708** to capture the reflected light from the tissue measurement site.

Advantageously, the light path **720** illustrated in FIG. **7**A depicts a substantial sample of reflected light that enter the light isolation chamber formed by the light blocker **706** and cover **707**. As previously discussed, the large sample of reflected light (as compared to the reflected light collected using the 2D point optical source approach) provides the opportunity to take an average of the detected light, to derive a more accurate measurement of the emitted light absorbed by the tissue, which will lead to a more accurate oxygen saturation measurement.

Referring now to FIG. **7**B, a top view of the 3D sensor **700** is illustrated with both the emitter **702** and the light blocker cover **707** removed for ease of illustration. The outer ring illustrates the footprint of the light diffuser **704**. As light is emitted from the emitter **702** (not shown in FIG. **7**B), it is diffused homogenously and directed to the tissue measurement site **102**. The light blocker **706** forms the circular wall of a light isolation chamber to keep incident light from being sensed by the detector **710**. The light blocker cover **707** blocks incidental light from entering the light isolation chamber from above. The light concentrator **710708** collects the reflected light from the tissue measurement site **102** and funnels it upward toward the detector **710** at the center of the 3D sensor **700**.

FIG. **8** illustrates an example of an optical physiological measurement system **800**, which may also be referred to herein as a pulse oximetry system **800**. In certain embodiments, the pulse oximetry system **800** noninvasively measures a blood analyte, such as oxygen, carboxyhemoglobin, methemoglobin, total hemoglobin, glucose, proteins, lipids, a percentage thereof (e.g., saturation), pulse rate, perfusion index, oxygen content, total hemoglobin, Oxygen Reserve Index™ (ORI™) or many other physiologically relevant patient characteristics. These characteristics can relate to, for example, pulse rate, hydration, trending information and analysis, and the like. The system **800** can also measure additional blood analytes and/or other physiological parameters useful in determining a state or trend of wellness of a patient.

The pulse oximetry system **800** can measure analyte concentrations at least in part by detecting optical radiation attenuated by tissue at a measurement site **102**. The measurement site **102** can be any location on a patient's body, such as a finger, foot, earlobe, wrist, forehead, or the like.

The pulse oximetry system **800** can include a sensor **801** (or multiple sensors) that is coupled to a processing device or physiological monitor **809**. In an embodiment, the sensor **801** and the monitor **809** are integrated together into a single unit. In another embodiment, the sensor **801** and the monitor **809** are separate from each other and communicate with one another in any suitable manner, such as via a wired or wireless connection. The sensor **801** and monitor **809** can be attachable and detachable from each other for the convenience of the user or caregiver, for ease of storage, sterility issues, or the like.

In the depicted embodiment shown in FIG. **8**, the sensor **801** includes an emitter **804**, a detector **806**, and a front-end interface **808**. The emitter **804** can serve as the source of optical radiation transmitted towards measurement site **102**. The emitter **804** can include one or more sources of optical radiation, such as light emitting diodes (LEDs), laser diodes, incandescent bulbs with appropriate frequency-selective filters, combinations of the same, or the like. In an embodiment, the emitter **804** includes sets of optical sources that are capable of emitting visible and near-infrared optical radiation.

The pulse oximetry system **800** also includes a driver **811** that drives the emitter **804**. The driver **111** can be a circuit or the like that is controlled by the monitor **809**. For example, the driver **811** can provide pulses of current to the emitter **804**. In an embodiment, the driver **811** drives the emitter **804** in a progressive fashion, such as in an alternating manner. The driver **811** can drive the emitter **804** with a series of pulses for some wavelengths that can penetrate tissue relatively well and for other wavelengths that tend to be significantly absorbed in tissue. A wide variety of other driving powers and driving methodologies can be used in various embodiments. The driver **811** can be synchronized with other parts of the sensor **801** to minimize or reduce jitter in the timing of pulses of optical radiation emitted from the emitter **804**. In some embodiments, the driver **811** is capable of driving the emitter **804** to emit optical radiation in a pattern that varies by less than about 10 parts-per-million.

The detector **806** captures and measures light from the tissue measurement site **102**. For example, the detector **806** can capture and measure light transmitted from the emitter **804** that has been attenuated or reflected from the tissue at the measurement site **102**. The detector **806** can output a detector signal **107** responsive to the light captured and measured. The detector **806** can be implemented using one

or more photodiodes, phototransistors, or the like. In some embodiments, a detector **806** is implemented in detector package to capture and measure light from the tissue measurement site **102** of the patient. The detector package can include a photodiode chip mounted to leads and enclosed in an encapsulant. In some embodiments, the dimensions of the detector package are approximately 2 square centimeters. In other embodiments, the dimensions of the detector package are approximately 1.5 centimeters in width and approximately 2 centimeters in length.

The front-end interface **808** provides an interface that adapts the output of the detectors **806**, which is responsive to desired physiological parameters. For example, the front-end interface **808** can adapt the signal **807** received from the detector **806** into a form that can be processed by the monitor **809**, for example, by a signal processor **810** in the monitor **809**. The front-end interface **808** can have its components assembled in the sensor **801**, in the monitor **809**, in a connecting cabling (if used), in combinations of the same, or the like. The location of the front-end interface **808** can be chosen based on various factors including space desired for components, desired noise reductions or limits, desired heat reductions or limits, and the like.

The front-end interface **808** can be coupled to the detector **806** and to the signal processor **810** using a bus, wire, electrical or optical cable, flex circuit, or some other form of signal connection. The front-end interface **808** can also be at least partially integrated with various components, such as the detectors **806**. For example, the front-end interface **808** can include one or more integrated circuits that are on the same circuit board as the detector **806**. Other configurations can also be used.

As shown in FIG. **8**, the monitor **909** can include the signal processor **810** and a user interface, such as a display **812**. The monitor **809** can also include optional outputs alone or in combination with the display **812**, such as a storage device **814** and a network interface **816**. In an embodiment, the signal processor **810** includes processing logic that determines measurements for desired analytes based on the signals received from the detector **806**. The signal processor **810** can be implemented using one or more microprocessors or sub-processors (e.g., cores), digital signal processors, application specific integrated circuits (ASICs), field programmable gate arrays (FPGAs), combinations of the same, and the like.

The signal processor **810** can provide various signals that control the operation of the sensor **801**. For example, the signal processor **810** can provide an emitter control signal to the driver **811**. This control signal can be useful in order to synchronize, minimize, or reduce jitter in the timing of pulses emitted from the emitter **804**. Accordingly, this control signal can be useful in order to cause optical radiation pulses emitted from the emitter **804** to follow a precise timing and consistent pattern. For example, when a transimpedance-based front-end interface **808** is used, the control signal from the signal processor **810** can provide synchronization with an analog-to-digital converter (ADC) in order to avoid aliasing, cross-talk, and the like. As also shown, an optional memory **813** can be included in the front-end interface **808** and/or in the signal processor **810**. This memory **813** can serve as a buffer or storage location for the front-end interface **808** and/or the signal processor **810**, among other uses.

The user interface **812** can provide an output, e.g., on a display, for presentation to a user of the pulse oximetry system **800**. The user interface **812** can be implemented as a touch-screen display, a liquid crystal display (LCD), an organic LED display, or the like. In alternative embodiments, the pulse oximetry system **800** can be provided without a user interface **812** and can simply provide an output signal to a separate display or system.

The storage device **814** and a network interface **816** represent other optional output connections that can be included in the monitor **809**. The storage device **814** can include any computer-readable medium, such as a memory device, hard disk storage, EEPROM, flash drive, or the like. The various software and/or firmware applications can be stored in the storage device **814**, which can be executed by the signal processor **810** or another processor of the monitor **809**. The network interface **816** can be a serial bus port (RS-232/RS-485), a Universal Serial Bus (USB) port, an Ethernet port, a wireless interface (e.g., WiFi such as any 802.1x interface, including an internal wireless card), or other suitable communication device(s) that allows the monitor **809** to communicate and share data with other devices. The monitor **809** can also include various other components not shown, such as a microprocessor, graphics processor, or controller to output the user interface **812**, to control data communications, to compute data trending, or to perform other operations.

Although not shown in the depicted embodiment, the pulse oximetry system **800** can include various other components or can be configured in different ways. For example, the sensor **801** can have both the emitter **804** and detector **806** on the same side of the tissue measurement site **102** and use reflectance to measure analytes.

Although the foregoing disclosure has been described in terms of certain preferred embodiments, many other variations than those described herein will be apparent to those of ordinary skill in the art.

Conditional language used herein, such as, among others, "can," "might," "may," "e.g.," and the like, unless specifically stated otherwise, or otherwise understood within the context as used, is generally intended to convey that certain embodiments include, while other embodiments do not include, certain features, elements and/or states. Thus, such conditional language is not generally intended to imply that features, elements and/or states are in any way required for one or more embodiments or that one or more embodiments necessarily include logic for deciding, with or without author input or prompting, whether these features, elements and/or states are included or are to be performed in any particular embodiment. The terms "comprising," "including," "having," and the like are synonymous and are used inclusively, in an open-ended fashion, and do not exclude additional elements, features, acts, operations, and so forth. Also, the term "or" is used in its inclusive sense (and not in its exclusive sense) so that when used, for example, to connect a list of elements, the term "or" means one, some, or all of the elements in the list. Further, the term "each," as used herein, in addition to having its ordinary meaning, can mean any subset of a set of elements to which the term "each" is applied.

While the above detailed description has shown, described, and pointed out novel features as applied to various embodiments, it will be understood that various omissions, substitutions, and changes in the form and details of the systems, devices or algorithms illustrated can be made without departing from the spirit of the disclosure. As will be recognized, certain embodiments of the disclosure described herein can be embodied within a form that does not provide all of the features and benefits set forth herein, as some features can be used or practiced separately from others.

The term "and/or" herein has its broadest, least limiting meaning which is the disclosure includes A alone, B alone, both A and B together, or A or B alternatively, but does not require both A and B or require one of A or one of B. As used herein, the phrase "at least one of" A, B, "and" C should be construed to mean a logical A or B or C, using a non-exclusive logical or.

The apparatuses and methods described herein may be implemented by one or more computer programs executed by one or more processors. The computer programs include processor-executable instructions that are stored on a non-transitory tangible computer readable medium. The computer programs may also include stored data. Non-limiting examples of the non-transitory tangible computer readable medium are nonvolatile memory, magnetic storage, and optical storage. Although the foregoing disclosure has been described in terms of certain preferred embodiments, other embodiments will be apparent to those of ordinary skill in the art from the disclosure herein. Additionally, other combinations, omissions, substitutions and modifications will be apparent to the skilled artisan in view of the disclosure herein. Accordingly, the present invention is not intended to be limited by the description of the preferred embodiments, but is to be defined by reference to claims.

Additionally, all publications, patents, and patent applications mentioned in this specification are herein incorporated by reference to the same extent as if each individual publication, patent, or patent application were specifically and individually indicated to be incorporated by reference.

What is claimed is:

1. A physiological monitoring device comprising:

a plurality of emitters configured to emit light in a first shape;

a material positioned between the plurality of emitters and a tissue measurement site on a wrist of a user when the physiological monitoring device is in use, the material configured to change the first shape into a second shape by which the light emitted from one or more of the plurality of emitters is projected towards a surface of the tissue measurement site;

a plurality of detectors configured to detect at least a portion of the light after passing through tissue, the plurality of detectors further configured to output at least one signal responsive to the detected light;

a surface comprising a dark-colored coating, the surface positioned between the plurality of detectors and the tissue when the physiological monitoring device is in use, wherein an opening defined in the dark-colored coating is configured to allow at least a portion of light reflected from the tissue to pass through the surface;

a light block configured to prevent at least a portion of the light emitted from the plurality of emitters from reaching the plurality of detectors without first reaching the tissue; and

a processor configured to receive and process one or more signals responsive to the at least one outputted signal and determine a physiological parameter of the user responsive to the one or more signals.

2. The physiological monitoring device of claim **1**, further comprising a display configured to present visual feedback responsive to the determined physiological parameter.

3. The physiological monitoring device of claim **2**, wherein the display is a touch-screen display.

4. The physiological monitoring device of claim **1**, wherein the plurality of emitters and the plurality of detectors are arranged in a reflectance measurement configuration.

5. The physiological monitoring device of claim **1**, wherein the plurality of detectors are arranged in an array having a spatial configuration corresponding to a shape of a portion of the tissue measurement site bounded by the light block.

6. The physiological monitoring device of claim **1**, wherein the light block comprises an at least partially circular shape, and wherein the plurality of emitters are positioned outside the light block and the plurality of detectors are positioned inside the light block.

7. The physiological monitoring device of claim **1**, wherein the physiological parameter comprises pulse rate.

8. The physiological monitoring device of claim **1**, wherein the physiological parameter comprises oxygen saturation.

9. The physiological monitoring device of claim **1**, wherein the material comprises plastic.

10. The physiological monitoring device of claim **1**, wherein the material comprises glass.

11. The physiological monitoring device of claim **1**, wherein the second shape comprises a circular geometry.

12. The physiological monitoring device of claim **1**, wherein the opening defined in the dark-colored coating comprises a width and a length, and wherein the width is larger than the length.

13. The physiological monitoring device of claim **1**, wherein the dark-colored coating comprises black.

14. A physiological monitoring device comprising:

a plurality of optical sources configured to emit light proximate a wrist of a user;

a diffuser configured to be positioned between the plurality of optical sources and a tissue measurement site on the wrist of the user when the physiological monitoring device is in use;

a light block having a circular shape;

a plurality of detectors configured to detect at least a portion of the light after the light passes through a portion of the tissue measurement site bounded by the light block, wherein the plurality of detectors are arranged in an array having a spatial configuration corresponding to a shape of the portion of the tissue measurement site bounded by the circular shaped light block, wherein the plurality of detectors are further configured to output at least one signal responsive to the detected light, and wherein the plurality of optical sources and the plurality of detectors are arranged in a reflectance measurement configuration;

wherein the light block is configured to prevent at least a portion of light emitted from the plurality of optical sources from reaching the plurality of detectors without first reaching tissue;

a processor configured to receive and process one or more signals responsive to the at least one outputted signal and determine a physiological parameter of the user responsive to the one or more signals; and

wherein the physiological monitoring device is configured to transmit physiological parameter data to a separate processor.

15. The physiological monitoring device of claim **14**, wherein the plurality of optical sources are positioned outside the light block and the plurality of detectors are positioned inside the light block.

16. The physiological monitoring device of claim **14**, wherein the physiological parameter comprises pulse rate.

17. The physiological monitoring device of claim **14**, wherein the physiological parameter comprises oxygen saturation.

18. The physiological monitoring device of claim 14, wherein the plurality of optical sources are configured to emit light in a first shape, and wherein the diffuser comprises a material configured to change the first shape into a second shape by which the light emitted from one or more of the plurality of optical sources is projected towards the tissue measurement site.

19. A system configured to measure one or more physiological parameters of a user, the system comprising:

a physiological monitoring device comprising:

a plurality of emitters configured to emit light in a first shape;

a material positioned between the plurality of emitters and a tissue measurement site when the physiological monitoring device is in use, the material configured to change the first shape into a second shape by which the light emitted from one or more of the plurality of emitters is projected towards the tissue measurement site;

a plurality of detectors configured to detect at least a portion of the light passing through tissue, the plurality of detectors further configured to output at least one signal responsive to the detected light;

a surface comprising a dark-colored coating, the surface positioned between the plurality of detectors and the tissue when the physiological monitoring device is in use, wherein an opening defined in the dark-colored coating is configured to allow at least a portion of light reflected from the tissue to pass through the surface;

a light block configured to prevent at least a portion of light from the plurality of emitters from reaching the plurality of detectors without first reaching the tissue; and

a processor configured to receive and process one or more signals responsive to the outputted at least one signal and determine a physiological parameter of the user responsive to the one or more signals; and

a processing device configured to wirelessly receive physiological parameter data from the physiological monitoring device, wherein the processing device comprises a user interface, a storage device, and a network interface configured to wirelessly communicate with the physiological monitoring device, and wherein the user interface includes a touch-screen display configured to present visual feedback responsive to the physiological parameter data.

20. The system of claim 19, wherein the system is configured to determine a state of wellness of the user based on the determined physiological parameter.

21. The system of claim 19, wherein the system is configured to determine a trend of wellness of the user based on the determined physiological parameter.

22. The system of claim 19, wherein the visual feedback presented by the touch-screen display is responsive to at least one of a pulse rate and an oxygen saturation of the user.

23. The system of claim 19, wherein the material comprises at least one of glass and plastic.

24. The system of claim 19, wherein the second shape comprises a width and a length, and wherein the width is different from the length.

25. The system of claim 19, wherein the plurality of detectors are arranged in an array having a spatial configuration corresponding to a shape of a portion of the tissue measurement site bounded by the light block.

* * * * *

US010736507B2

(12) **United States Patent**
Muhsin et al.

(10) **Patent No.: US 10,736,507 B2**
(45) **Date of Patent: Aug. 11, 2020**

(54) **PHYSIOLOGICAL MONITOR WITH MOBILE COMPUTING DEVICE CONNECTIVITY**

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(73) Assignee: **Masimo Corporation**, Irvine, CA (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: **15/880,071**

(22) Filed: **Jan. 25, 2018**

(65) **Prior Publication Data**

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Related U.S. Application Data

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(60) Provisional application No. 61/703,729, filed on Sep. 20, 2012.

(51) **Int. Cl.**

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A61B 5/0476	(2006.01)
A61B 5/0402	(2006.01)
A61B 5/0205	(2006.01)
A61B 5/00	(2006.01)
A61B 7/00	(2006.01)

(52) **U.S. Cl.**

CPC ***A61B 5/0002*** (2013.01); ***A61B 5/02055*** (2013.01); ***A61B 5/0402*** (2013.01); ***A61B 5/0476*** (2013.01); ***A61B 5/14551*** (2013.01); ***A61B 5/7203*** (2013.01); ***A61B 5/7225*** (2013.01); ***A61B 5/742*** (2013.01); *A61B 7/003* (2013.01); *A61B 2562/22* (2013.01)

(58) **Field of Classification Search**

None

See application file for complete search history.

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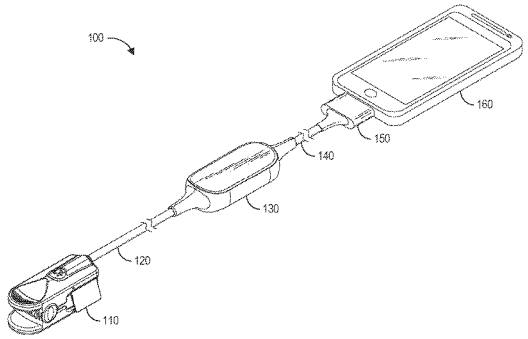
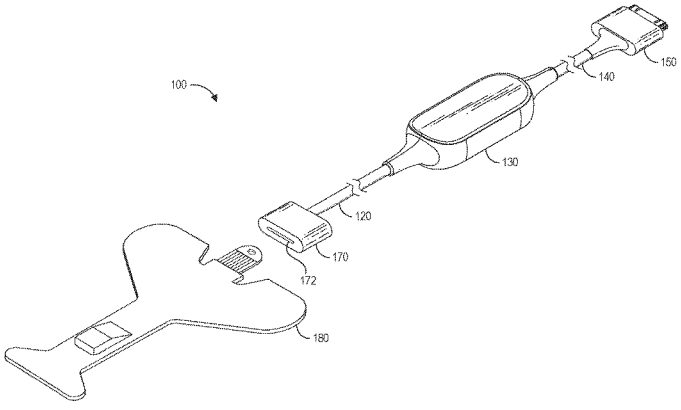
Primary Examiner — Eric F Winakur
Assistant Examiner — Marjan Fardanesh
(74) *Attorney, Agent, or Firm* — Knobbe, Martens, Olson & Bear, LLP

(57) **ABSTRACT**

Systems and method for monitoring patient physiological data are presented herein. In one embodiment, a physiological sensor and a mobile computing device can be connected via a cable or cables, and a processing board can be connected between the sensor and the mobile computing device to conduct advanced signal processing on the data received from the sensor before the data is transmitted for display on the mobile computing device.

20 Claims, 15 Drawing Sheets





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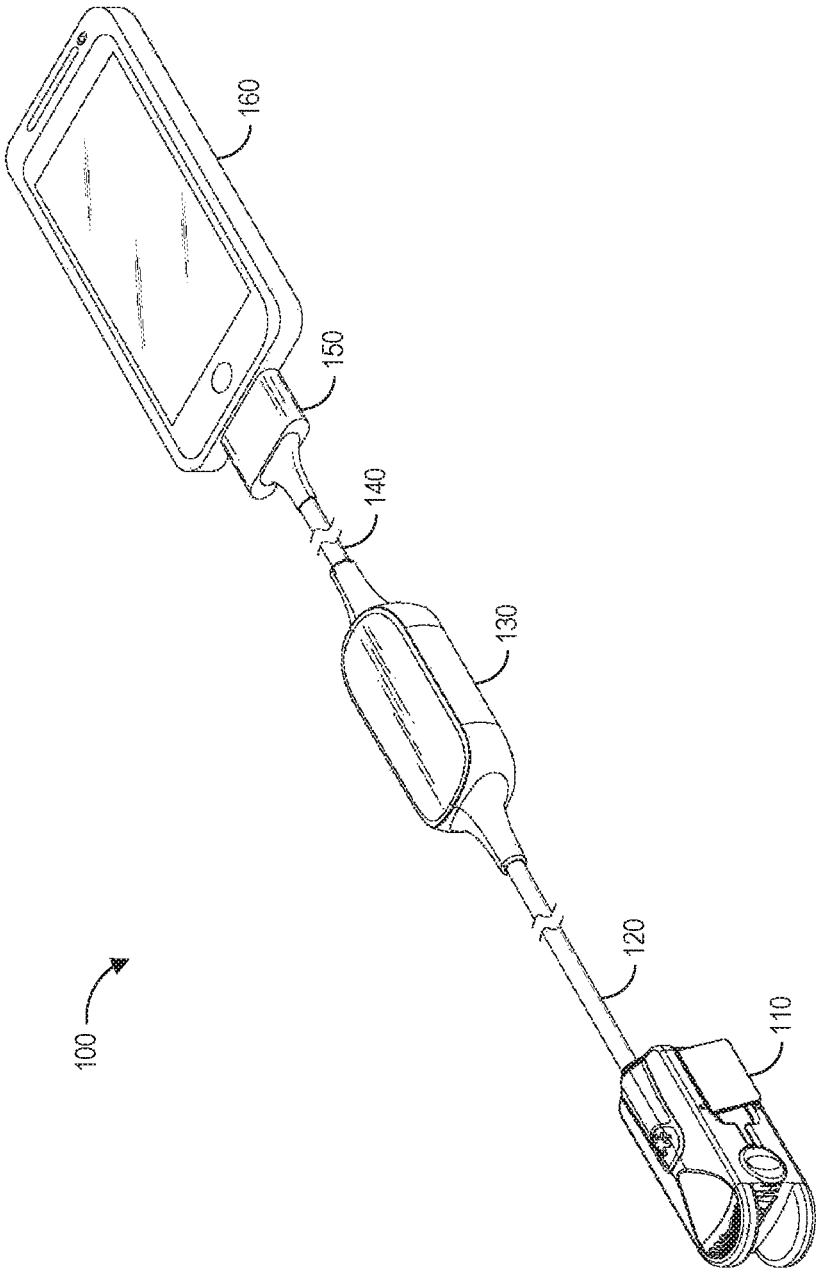

FIG. 1A

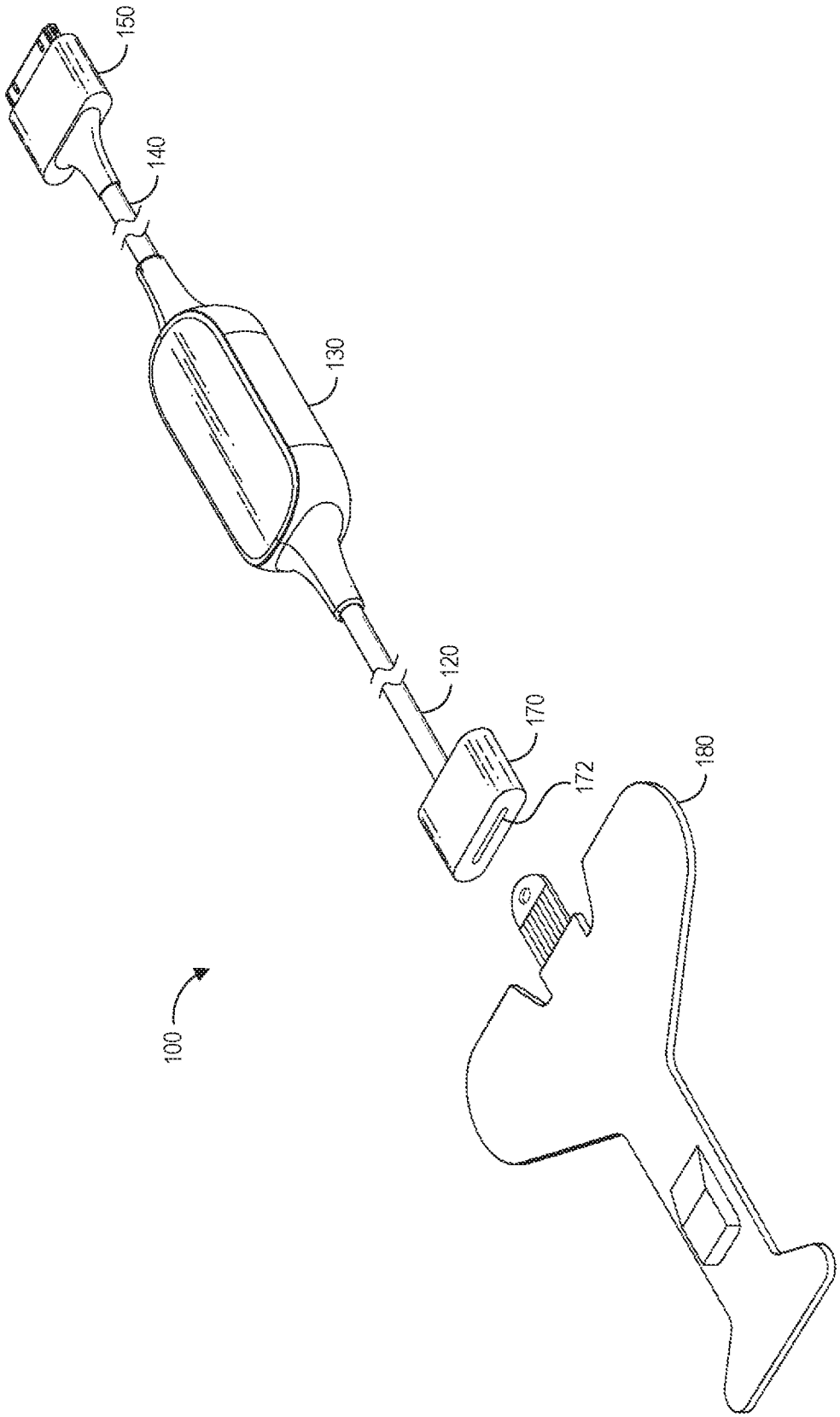

FIG. 1B

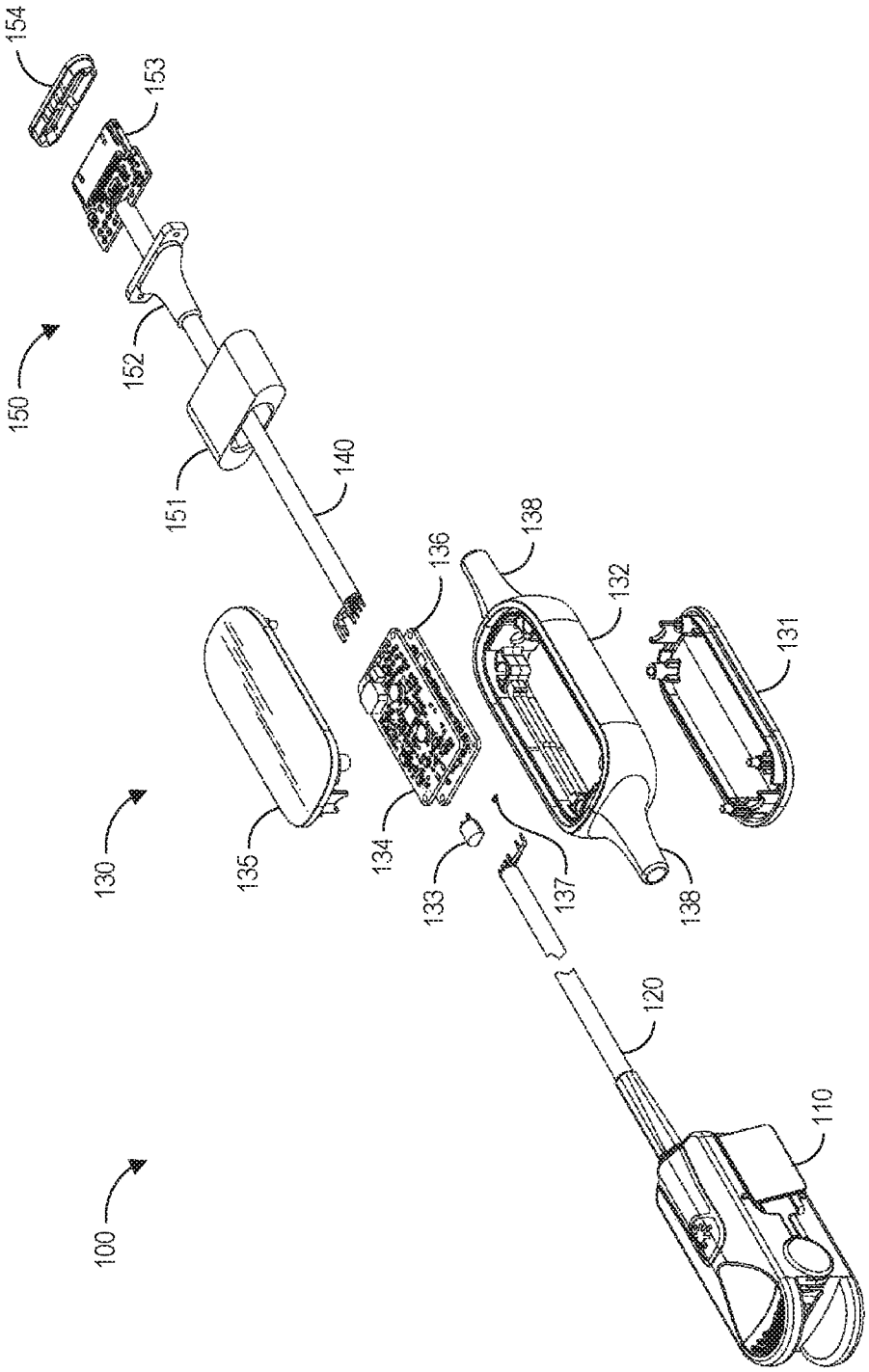
154
153
152
150
151
140
136
138
132
131
135
134
133
137
138
130
120
110
100

FIG. 1C

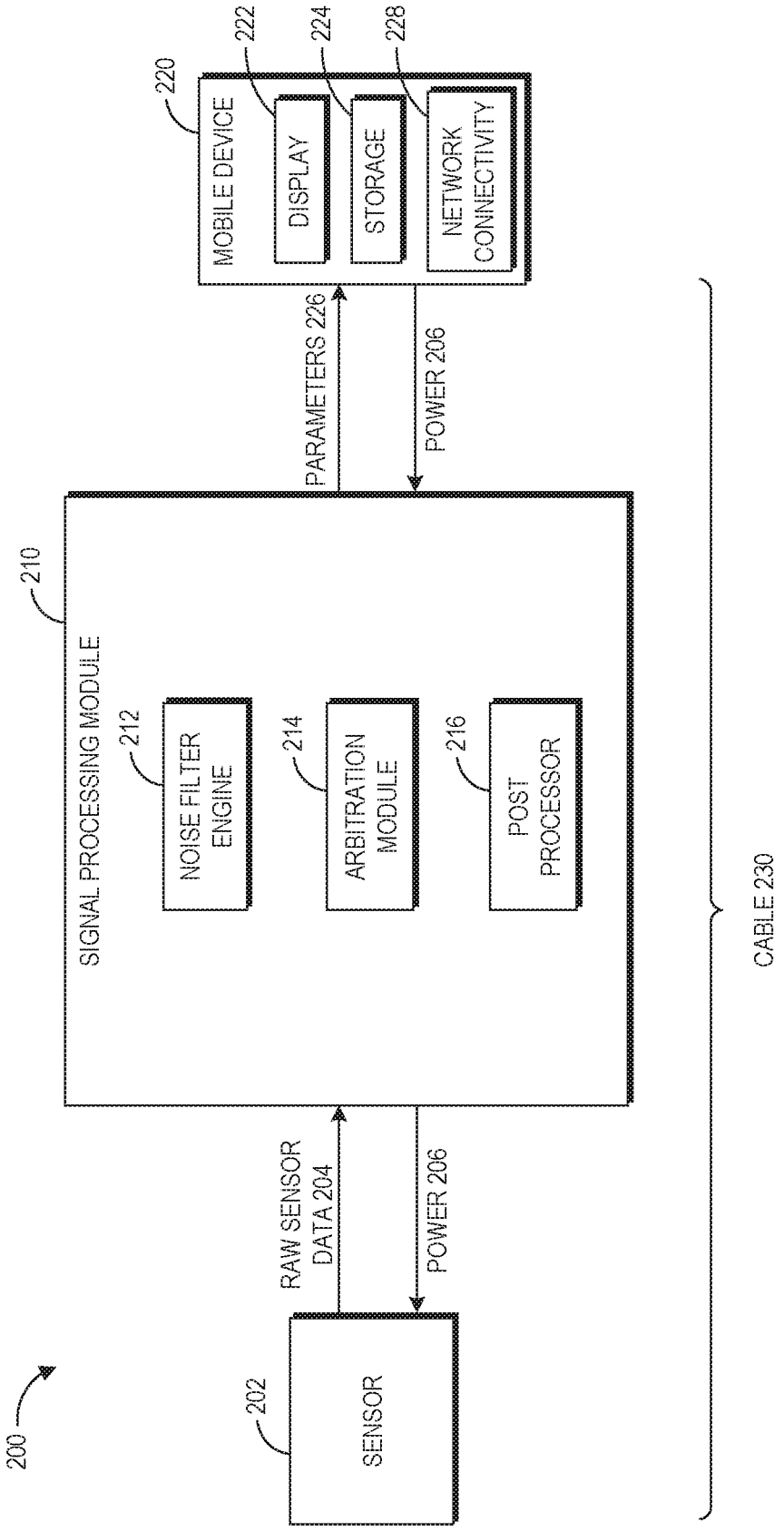
200
202
SENSOR
RAW SENSOR DATA 204
POWER 206
210
SIGNAL PROCESSING MODULE
212
NOISE FILTER ENGINE
214
ARBITRATION MODULE
216
POST PROCESSOR
CABLE 230
PARAMETERS 226
POWER 206
220
MOBILE DEVICE
222
DISPLAY
224
STORAGE
228
NETWORK CONNECTIVITY

FIG. 2

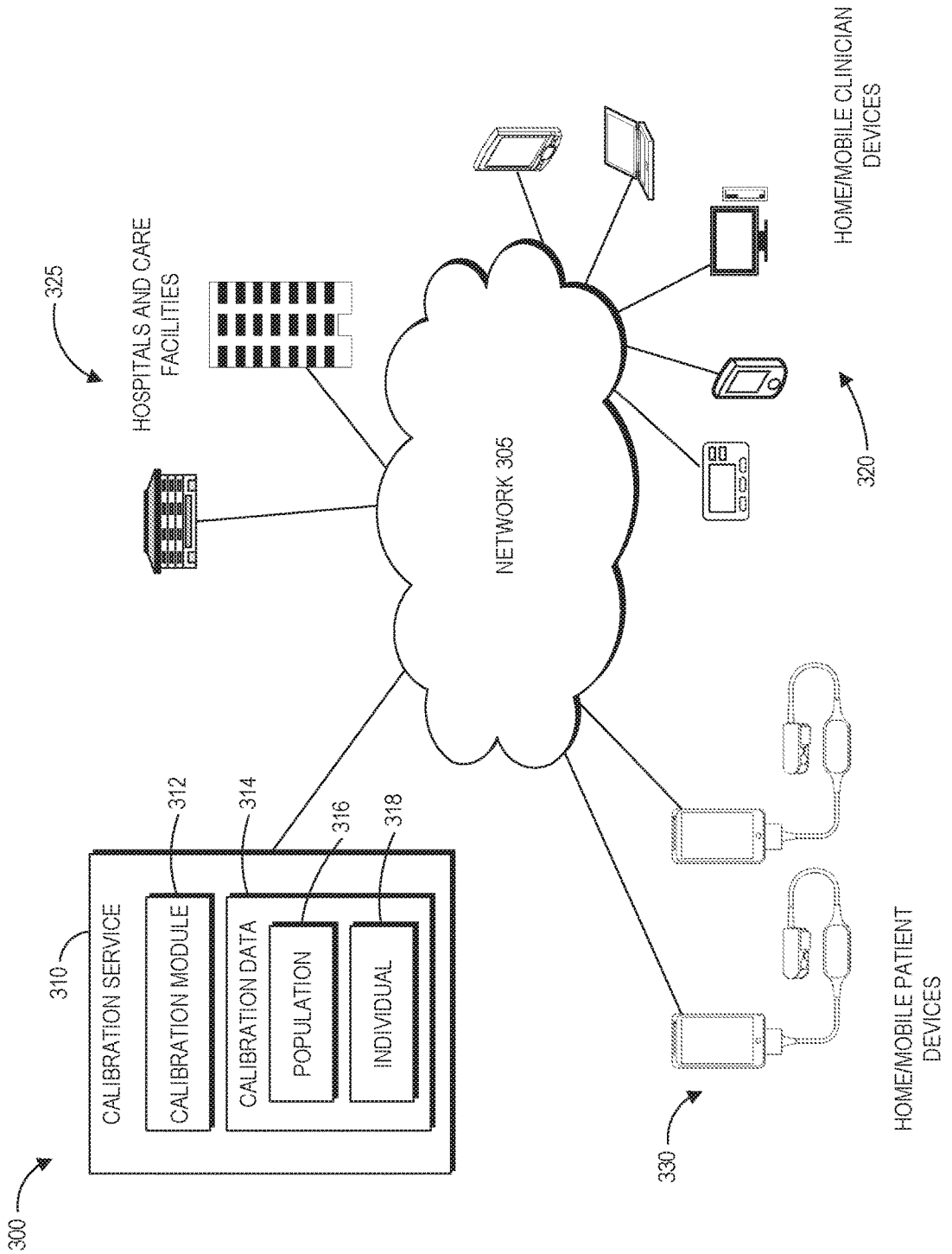
300
310
CALIBRATION SERVICE
CALIBRATION MODULE
CALIBRATION DATA
POPULATION
INDIVIDUAL
312
314
316
318
NETWORK 305
325
HOSPITALS AND CARE FACILITIES
320
HOME/MOBILE CLINICIAN DEVICES
330
HOME/MOBILE PATIENT DEVICES

FIG. 3

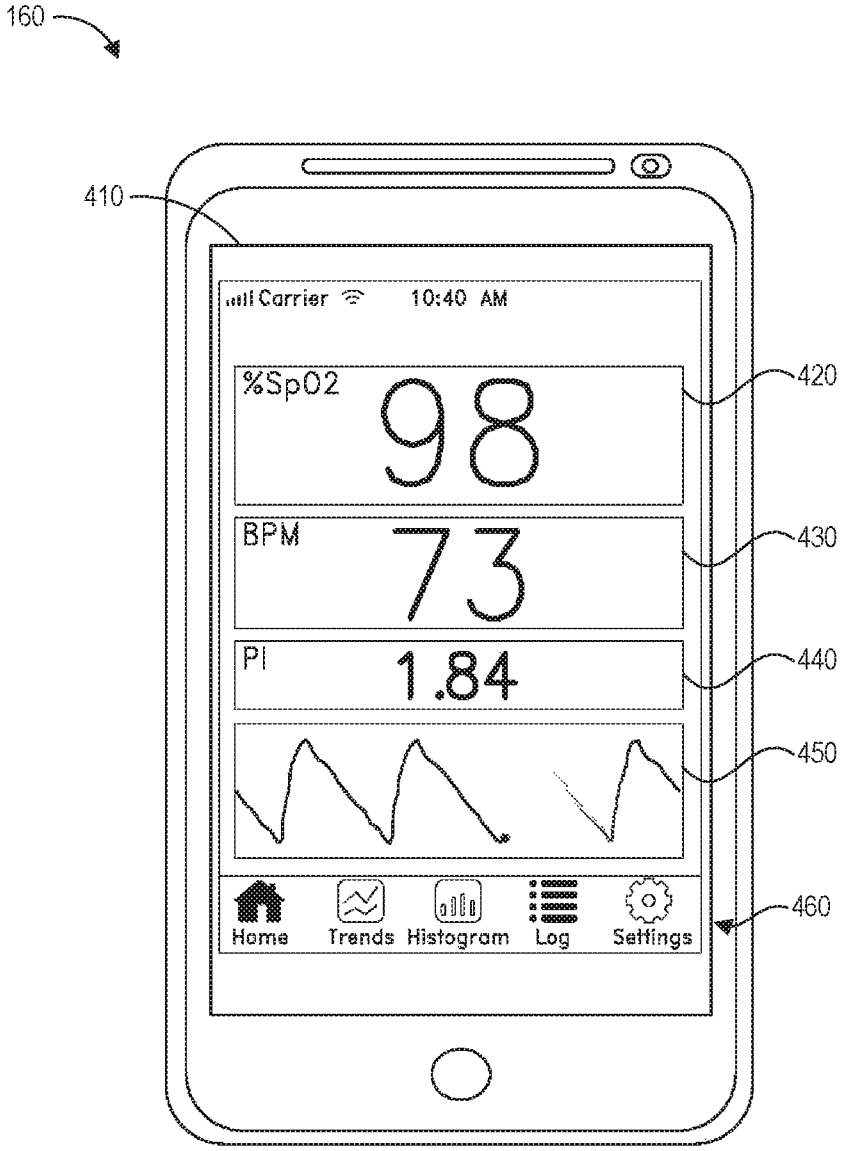
160
410
Carrier
10:40 AM
%SpO2
98
420
BPM
73
430
PI
1.84
440
450
Home
Trends
Histogram
Log
Settings
460

FIG. 4A

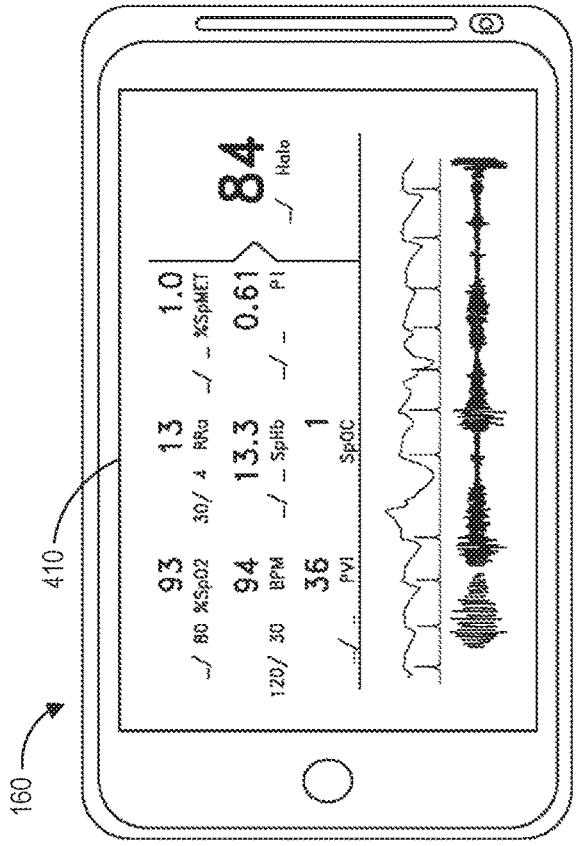
160
410
93
%SpO2
94
BPM
36
PVI
13
RRa
13.3
SpHb
1
SpOC
1.0
%SpMET
0.61
PI
84
Hale

FIG. 4B

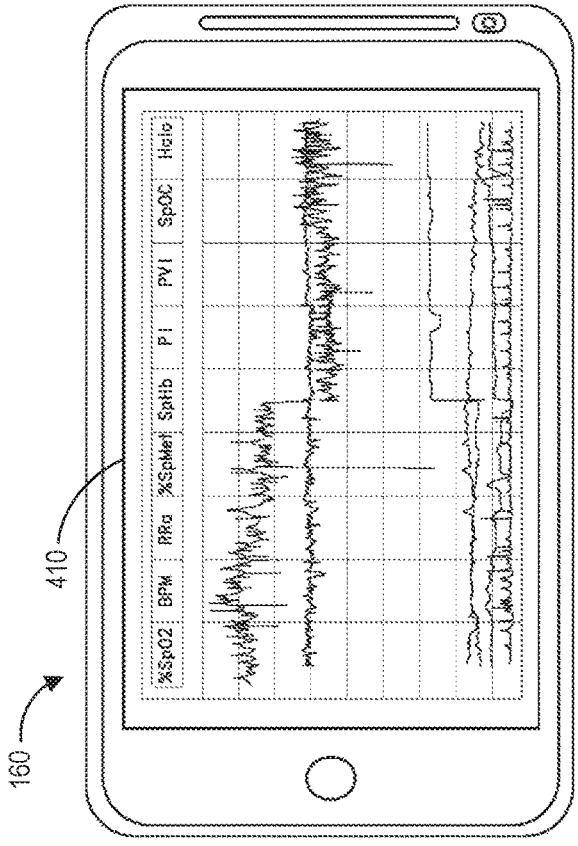
160
410
%SpO2
BPM
RRa
%SpMet
SpHb
PI
PVI
SpOC
Hale

FIG. 4C

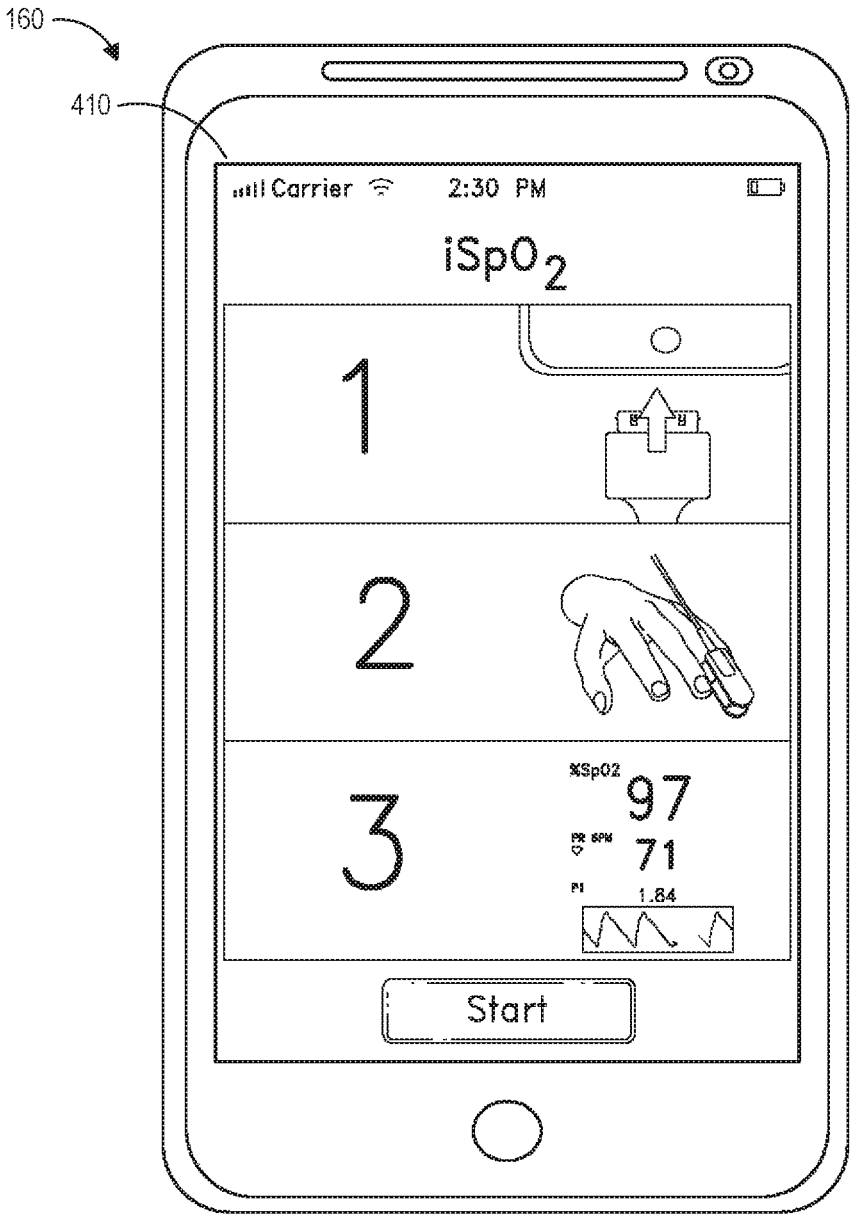

FIG. 4D

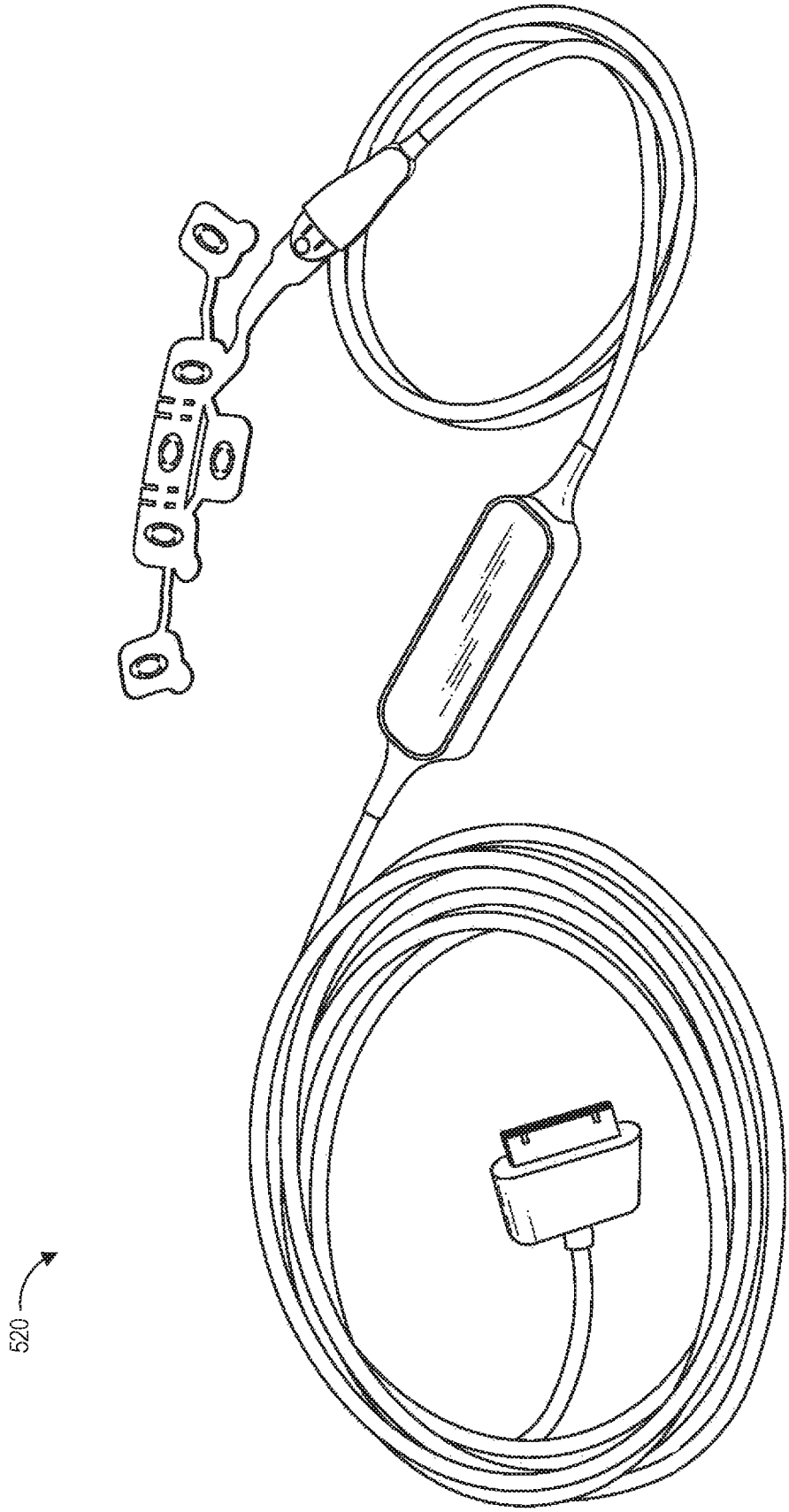

FIG. 5A

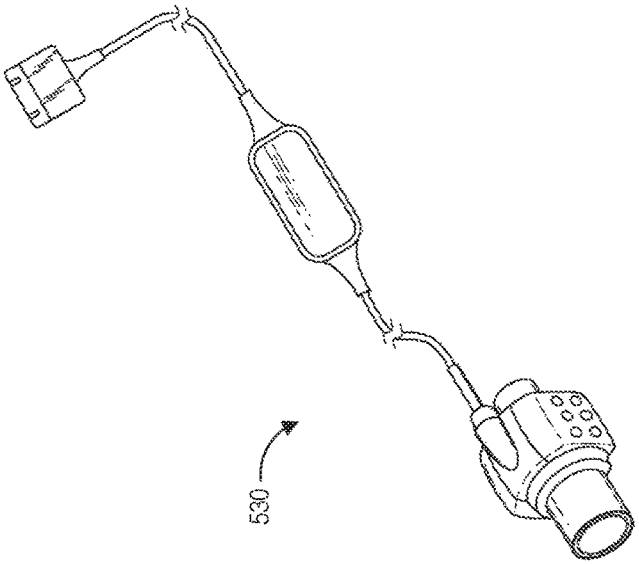

FIG. 5B

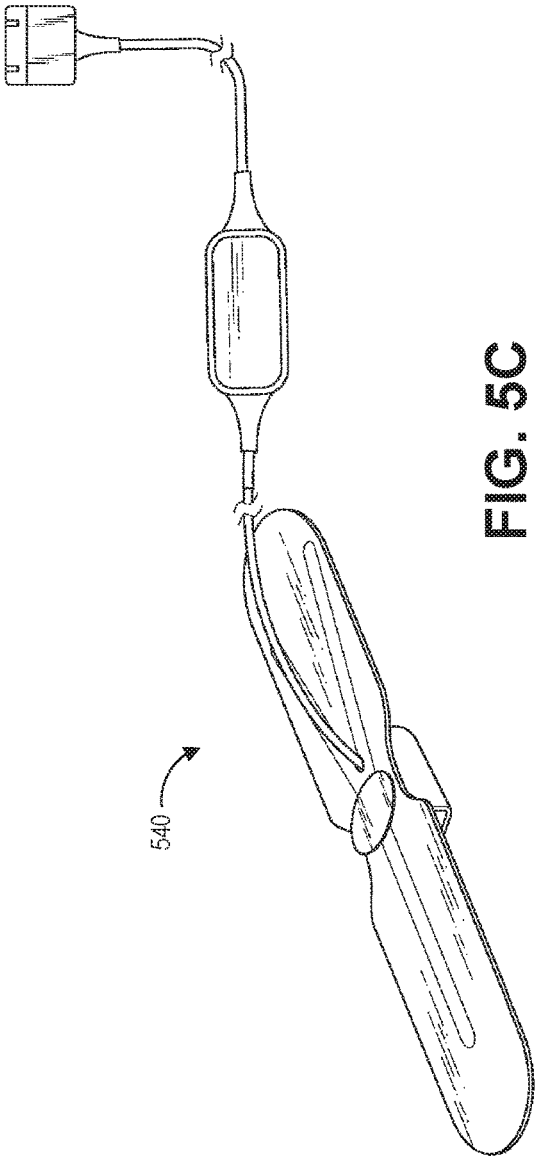

FIG. 5C

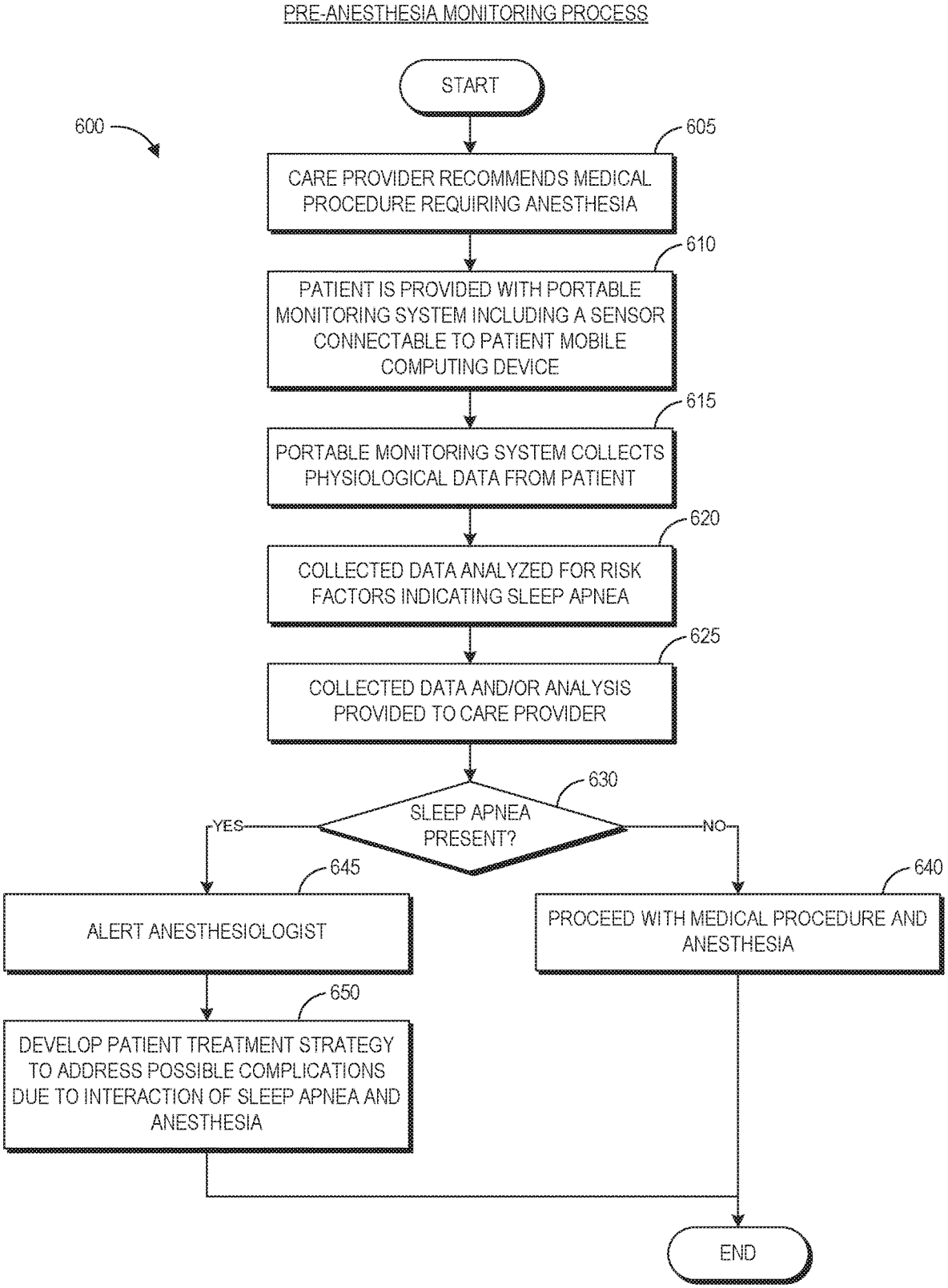
PRE-ANESTHESIA MONITORING PROCESS
600
START
605
CARE PROVIDER RECOMMENDS MEDICAL PROCEDURE REQUIRING ANESTHESIA
610
PATIENT IS PROVIDED WITH PORTABLE MONITORING SYSTEM INCLUDING A SENSOR CONNECTABLE TO PATIENT MOBILE COMPUTING DEVICE
615
PORTABLE MONITORING SYSTEM COLLECTS PHYSIOLOGICAL DATA FROM PATIENT
620
COLLECTED DATA ANALYZED FOR RISK FACTORS INDICATING SLEEP APNEA
625
COLLECTED DATA AND/OR ANALYSIS PROVIDED TO CARE PROVIDER
630
SLEEP APNEA PRESENT?
YES
NO
645
ALERT ANESTHESIOLOGIST
640
PROCEED WITH MEDICAL PROCEDURE AND ANESTHESIA
650
DEVELOP PATIENT TREATMENT STRATEGY TO ADDRESS POSSIBLE COMPLICATIONS DUE TO INTERACTION OF SLEEP APNEA AND ANESTHESIA
END

FIG. 6

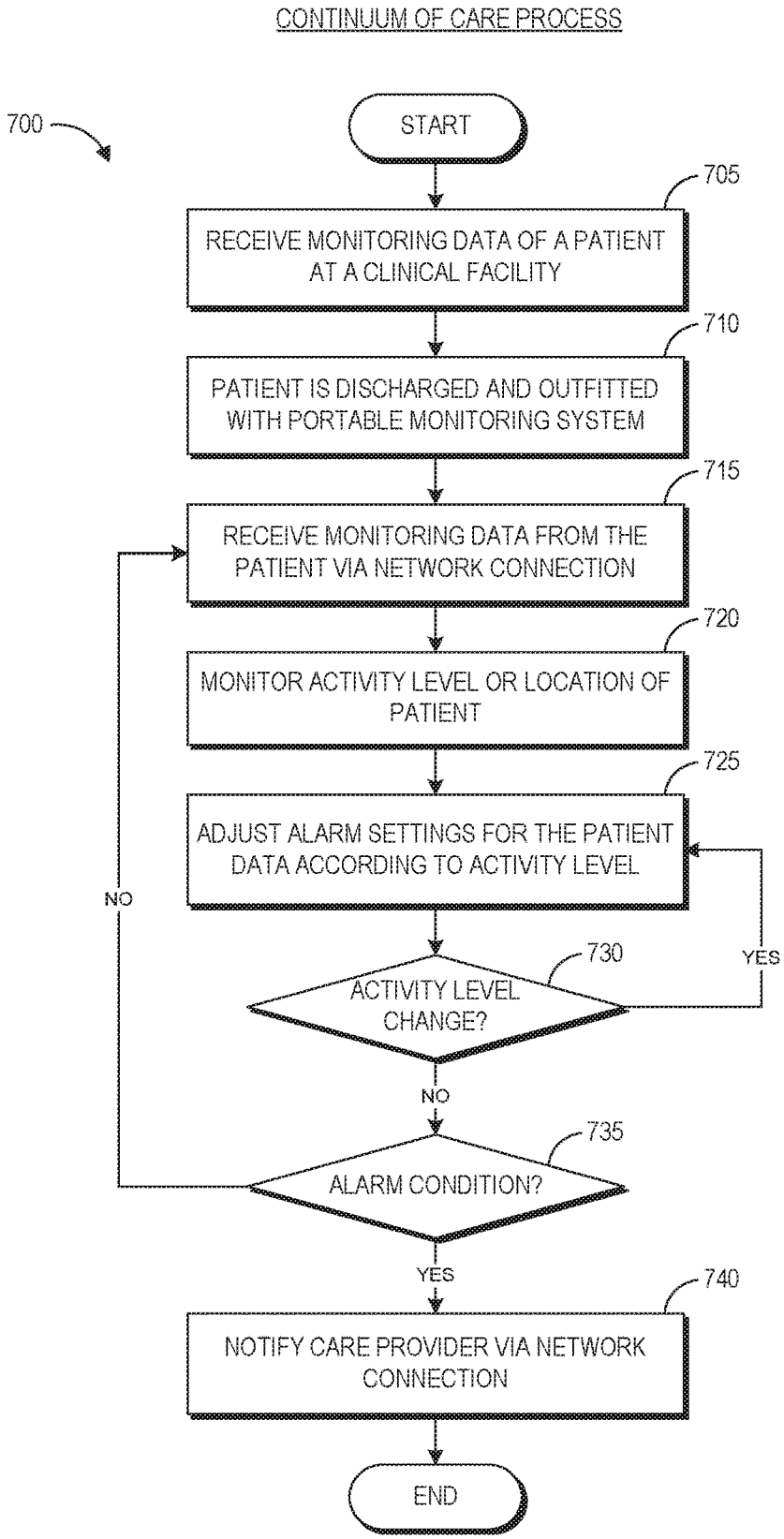
CONTINUUM OF CARE PROCESS
700
START
705
RECEIVE MONITORING DATA OF A PATIENT AT A CLINICAL FACILITY
710
PATIENT IS DISCHARGED AND OUTFITTED WITH PORTABLE MONITORING SYSTEM
715
RECEIVE MONITORING DATA FROM THE PATIENT VIA NETWORK CONNECTION
720
MONITOR ACTIVITY LEVEL OR LOCATION OF PATIENT
725
ADJUST ALARM SETTINGS FOR THE PATIENT DATA ACCORDING TO ACTIVITY LEVEL
730
ACTIVITY LEVEL CHANGE?
YES
NO
735
ALARM CONDITION?
NO
YES
740
NOTIFY CARE PROVIDER VIA NETWORK CONNECTION
END

FIG. 7

MOBILE PHYSIOLOGICAL DATA MONITORING

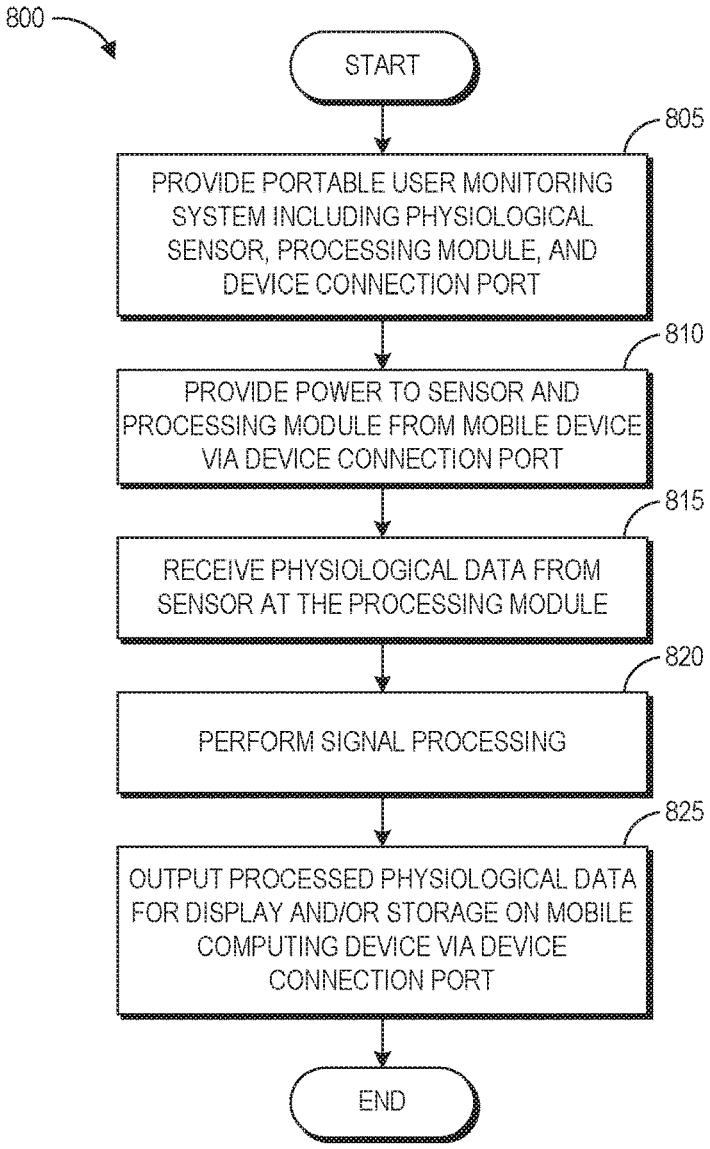

FIG. 8

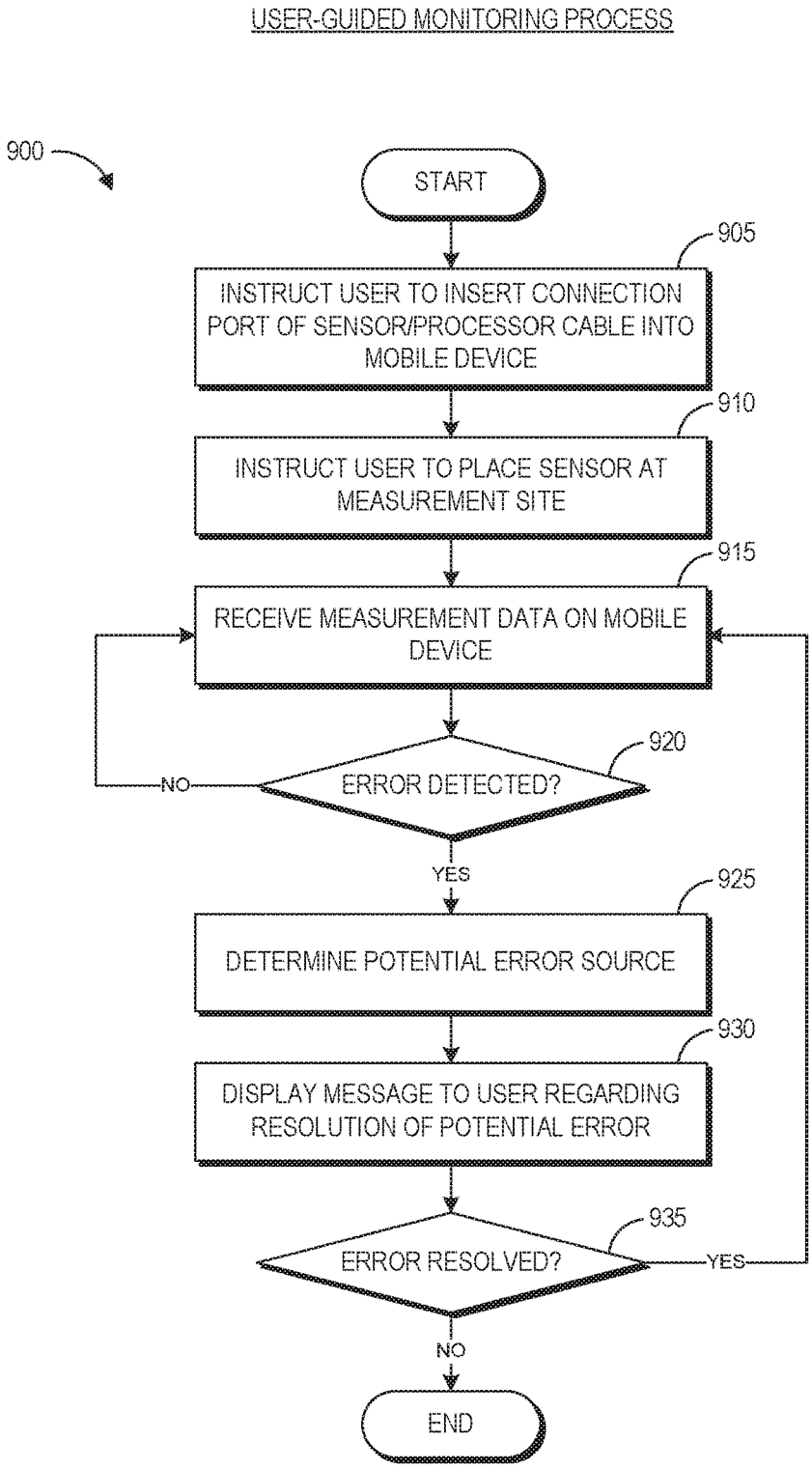
USER-GUIDED MONITORING PROCESS
900
START
905
INSTRUCT USER TO INSERT CONNECTION PORT OF SENSOR/PROCESSOR CABLE INTO MOBILE DEVICE
910
INSTRUCT USER TO PLACE SENSOR AT MEASUREMENT SITE
915
RECEIVE MEASUREMENT DATA ON MOBILE DEVICE
920
ERROR DETECTED?
NO
YES
925
DETERMINE POTENTIAL ERROR SOURCE
930
DISPLAY MESSAGE TO USER REGARDING RESOLUTION OF POTENTIAL ERROR
935
ERROR RESOLVED?
YES
NO
END

FIG. 9

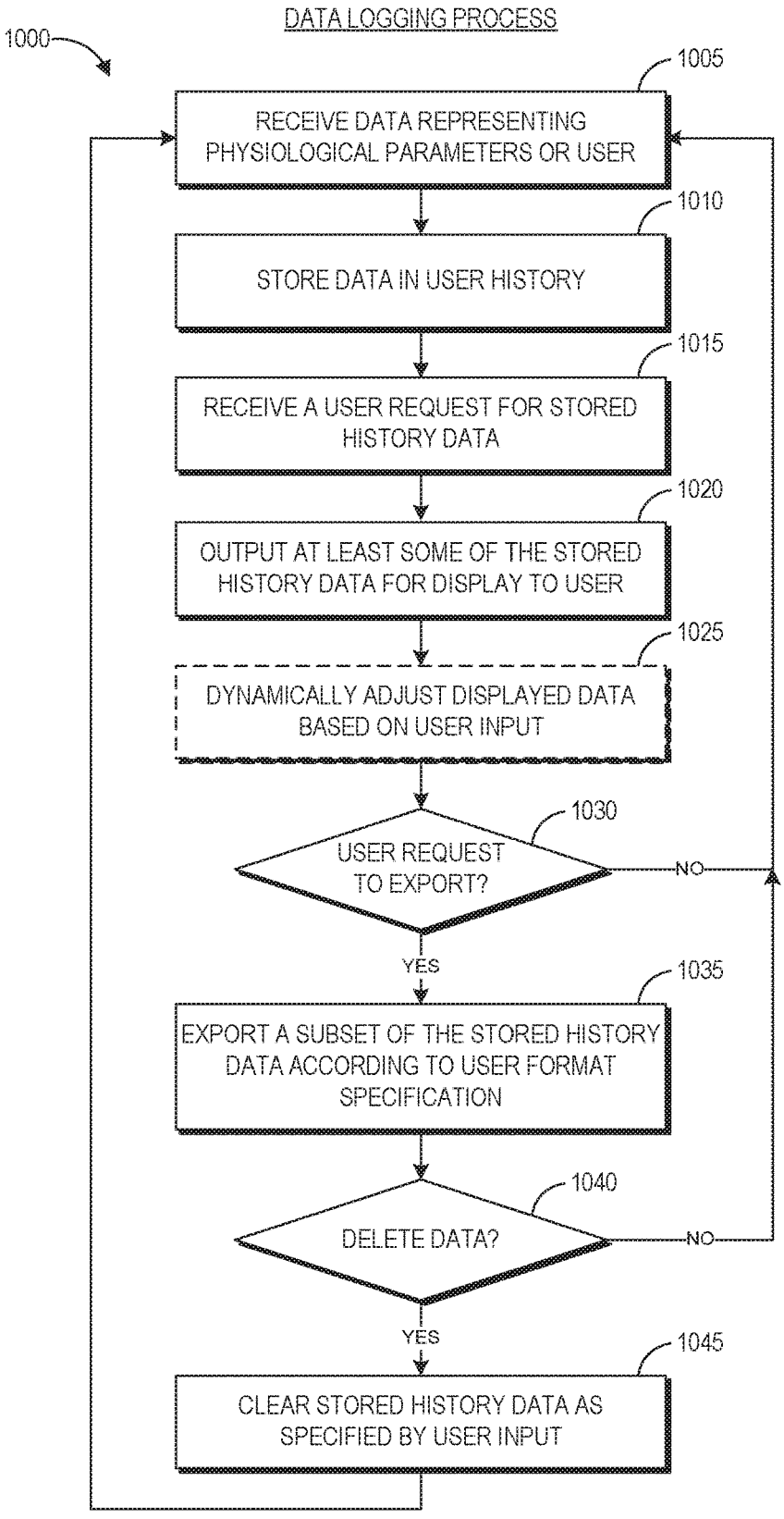
DATA LOGGING PROCESS
1000
1005
RECEIVE DATA REPRESENTING PHYSIOLOGICAL PARAMETERS OR USER
1010
STORE DATA IN USER HISTORY
1015
RECEIVE A USER REQUEST FOR STORED HISTORY DATA
1020
OUTPUT AT LEAST SOME OF THE STORED HISTORY DATA FOR DISPLAY TO USER
1025
DYNAMICALLY ADJUST DISPLAYED DATA BASED ON USER INPUT
1030
USER REQUEST TO EXPORT?
NO
YES
1035
EXPORT A SUBSET OF THE STORED HISTORY DATA ACCORDING TO USER FORMAT SPECIFICATION
1040
DELETE DATA?
NO
YES
1045
CLEAR STORED HISTORY DATA AS SPECIFIED BY USER INPUT

FIG. 10

PHYSIOLOGICAL MONITOR WITH MOBILE COMPUTING DEVICE CONNECTIVITY

RELATED APPLICATIONS

This application is a continuation of U.S. application Ser. No. 14/033,315, filed Sep. 20, 2013, entitled "PHYSIOLOGICAL MONITOR WITH MOBILE COMPUTING DEVICE CONNECTIVITY," which claims the benefit of U.S. Provisional Application No. 61/703,729 filed Sep. 20, 2012, entitled "Patient Monitor with Mobile Computing Device Connectivity," the disclosures of which are hereby incorporated by reference in their entirety.

BACKGROUND

Field of the Disclosure

The present disclosure relates in general to noninvasive patient monitoring systems, including oximeters and co-oximeters, and their accessories such as sensors or cables. In particular, this disclosure relates to patient monitors capable of connectivity to a mobile computing device.

Description of the Related Art

Oximetry utilizes a noninvasive optical sensor to measure physiological parameters of a patient. In general, the sensor has light emitting diodes (LEDs) that transmit optical radiation into a tissue site and a detector that responds to the intensity of the optical radiation after absorption (e.g., by transmission or transreflectance) by, for example, pulsatile arterial blood flowing within the tissue site. Based on this response, a processor determines measurements for oxygen saturation (SpO_2), pulse rate, plethysmograph waveforms, perfusion quality index (e.g., an index that quantifies perfusion), assessments of other blood constituents, parameters or analytes, including for example, a percent value for arterial carbon monoxide saturation (HbCO), a percent value for methemoglobin saturation (a brownish-red form of hemoglobin that cannot function as an oxygen carrier) (HbMet), total hemoglobin (HbT), fractional SpO_2 ($SpaO_2$) or the like. Additionally, caregivers often desire knowledge of HbO_2, Hb, blood glucose (HbGu), water, the presence or absence of therapeutic drugs (aspirin, Dapson, nitrates, or the like) or abusive/recreational drugs (methamphetamine, alcohol, steroids, or the like), concentrations of carbon dioxide (CO_2), oxygen (O_2), oxygen concentration, pH levels, bilirubin, perfusion quality, albumin, cyanmethemoglobin, and sulfhemoglobin (HbSulf), signal quality or the like. It is noted that "oximetry" as used herein encompasses its broad ordinary meaning known to one of skill in the art, which includes at least those noninvasive procedures for measuring parameters of circulating blood through spectroscopy. Moreover, "plethysmograph" as used herein (commonly referred to as "photoplethysmograph"), encompasses its broad ordinary meaning known to one of skill in the art, which includes at least data representative of a change in the absorption of particular wavelengths of light as a function of the changes in body tissue resulting from pulsing blood.

Oximeters capable of reading many of the foregoing parameters during noise due to patient movement, electromagnetic interference, and ambient light are available from Masimo Corporation (Masimo) of Irvine, Calif. Moreover, portable and other oximeters are disclosed in at least U.S. Pat. Nos. 6,770,028, 6,658,276, 6,157,850, 6,002,952, and 5,769,785, incorporated by reference herein, and others patent publications such as those listed at http://www.masimo.com/patents.htm. Such noise filtering oximeters have gained rapid acceptance in a wide variety of medical applications, including surgical wards, intensive care and neonatal units, general wards, home care, physical training, and virtually all types of monitoring scenarios. Some blood parameter monitors including oximeters are the standard of care in certain critical environments like surgery and neonatal care.

SUMMARY

Mobility and ease of use are key factors in the health care industry because they correlate to efficient, rapid patient care as well as enable patients to participate in their own care. Therefore, the present disclosure provides physiological monitoring devices which are compatible with handheld monitors such as common mobile computing devices for ease of use and portability.

This disclosure describes embodiments of a mobile physiological sensor that can be conveniently used in conjunction with existing mobile devices of users in a variety of contexts. In certain embodiments, a physiological monitoring system can be designed to include a sensor and cable assembly with a processing board or card, and the system can be connectable to a mobile computing device, such as a smartphone, such that display of the monitored physiological data can occur on the computing device. The board or card can communicate the data for display with the mobile computing device wirelessly or through a physical and electrical connection with the cable assembly. In some embodiments, the board or card can include one or more signal processors and associated memory, I/O, and the like to provide monitored physiological data to applications executing on traditional smartphone processing environments, such that board or card handles advanced signal processing and the smartphone displays parameter data. In an embodiment, the board is house in a portion of the cable such that it is not directly coupled to the sensor or the smartphone connector. This configuration has the advantage of mechanically isolating the board so that it does not encumber the sensor or the smart phone connection. As a result, the physiological monitoring system can be more portable than existing monitoring systems, thereby facilitating enhanced patient care for more patients.

For example, such a system can be sent home with a patient to gather physiological measurement data outside the hospital setting. In addition, portable physiological monitoring equipment as disclosed herein can facilitate the gathering of physiological measurement data in a variety of other contexts, such as sports or extreme sports, military training and combat, aviation, health awareness, high-altitude activities, monitoring of professionals in dangerous conditions, screening for medical conditions such as congenital heart defects, field hospitals, and mobile medical clinics, to name a few.

Physiological monitoring systems such as are described herein enable oximeter use outside of the traditional hospital setting. This is beneficial for more comprehensive patient care. For instance, prior to a surgical procedure during which a patient will be sedated, such as by general anesthesia, a physician can be concerned about the patient's proclivity toward apnea. A portable oximetry sensor compatible with the patient's smartphone can be sent home with the patient prior to the procedure, and the sensor can be worn overnight. Data collected from the sensor can be passed to the smart-

phone and made available to the doctor, such as by uploading to the internet or being downloadable from the device, to identify a risk of hypoxemia. This example illustrates one of the many benefits of a portable oximetry system compatible with a common mobile computing device.

For purposes of summarizing the disclosure, certain aspects, advantages and novel features of the inventions have been described herein. It is to be understood that not necessarily all such advantages can be achieved in accordance with any particular embodiment of the inventions disclosed herein. Thus, the inventions disclosed herein can be embodied or carried out in a manner that achieves or optimizes one advantage or group of advantages as taught herein without necessarily achieving other advantages as can be taught or suggested herein.

BRIEF DESCRIPTION OF THE DRAWINGS

Throughout the drawings, reference numbers can be reused to indicate correspondence between referenced elements. The drawings are provided to illustrate embodiments of the inventions described herein and not to limit the scope thereof.

FIG. **1**A illustrates an embodiment of a physiological monitoring system.

FIG. **1**B illustrates another embodiment of a physiological monitoring system.

FIG. **1**C illustrates an exploded view of one embodiment of the cable components of FIG. **1**A.

FIG. **2** illustrates a block diagram of an embodiment of a mobile physiological monitoring system.

FIG. **3** illustrates an embodiment of a computing environment in which a mobile patient monitoring device can communicate with various computing devices and services over a network.

FIGS. **4**A-**4**D illustrate various embodiments of software applications for display and management of physiological monitoring data.

FIGS. **5**A-**5**C illustrate various embodiments of mobile physiological sensors assemblies.

FIG. **6** illustrates an embodiment of a pre-anesthesia monitoring process.

FIG. **7** illustrates an embodiment of a continuum of care process.

FIG. **8** illustrates an embodiment of a mobile physiological data monitoring process.

FIG. **9** illustrates an embodiment of a user-guided monitoring process.

FIG. **10** illustrates an embodiment of a data-logging process.

DETAILED DESCRIPTION

I. Example Mobile Physiological Monitoring Systems

FIGS. **1**A, **1**B, and **1**C illustrate embodiments of a physiological monitoring system **100**. The physiological monitoring system **100** shown in FIG. **1**A includes a sensor **110**, first cable **120**, processing module **130**, second cable **140**, connection port **150**, and a mobile computing device, illustrated here as smartphone **160**. Although specific reference can be made to smartphones in this disclosure, any mobile computing device compatible with the physiological sensor system can be used. A compatible mobile computing device can be one of a wide range of mobile devices such as a mobile communications device (such as a smartphone), laptop, tablet computer, netbook, PDA, media player, mobile game console, wristwatch, wearable computing device, or other microprocessor based device configured to interface with a physiological sensor. Some embodiments of the mobile computing device can be used with the system for display of data and/or storage of data. Cables **120**, **140** used with the device can be flex cables or other cables, including cables having triboelectric properties.

As illustrated, the sensor **110** can be a pulse oximeter capable of being secured to a digit such as a finger, for example the Masimo Rainbow® pulse oximeter. However, this is for illustrative purposes only, and the sensor **110** can be any physiological sensor. In some embodiments, other varieties of pulse oximeters can be used, for example adhesive sensors, combination reusable/disposable sensors, soft and/or flexible wrap sensors, infant or pediatric sensors, multisite sensors, or sensors shaped for measurement at a tissue site such as an ear. In other embodiments, the sensor **110** can be any of a variety of sensors, such as a pulse oximeter, a brain function monitor such as an electroencephalograph ("EEG"), a gas monitor such as a capnometer or capnograph, an acoustic respiratory sensor, a heart function monitor such as an electrocardiograph ("ECG"), blood alcohol level sensors, temperature sensors, respiratory inductive plethysmography bands, bioelectric sensors, electronic fetal monitors, or the like. The sensor **110** can be reusable in some embodiments, can be disposable in some embodiments, and in other embodiments the sensor **110** can have both reusable and disposable components. In some embodiments, the sensor can be available in different sizes.

As illustrated in FIG. **1**B, in an embodiment, cable **120** can include a port **170** at the sensor-facing end of the cable **120**, and a disposable, connectable sensor **180** may be attached to the cable **120**. In some embodiments, the connectable sensor **180** can be reusable, or can be partially reusable and partially disposable. A sensor connection mechanism **172** can be configured to receive, or otherwise connect to, connectable sensors of different types, such as any of the physiological sensors discussed above. Although connection port **150** is illustrated as being configured for physical and electrical connection to a mobile device, in some embodiments, the connection port may be a wireless connection port configured to wirelessly transmit filtered physiological parameter data to the mobile device or another computing device.

In various oximeter embodiments, the sensor **110** provides data in the form of an output signal indicative of an amount of attenuation of predetermined wavelengths (ranges of wavelengths) of light by body tissues, such as, for example, a digit, portions of the nose or ear, a foot, or the like. The predetermined wavelengths often correspond to specific physiological parameter data desired, including for example, blood oxygen information such as oxygen content ("SpOC"), oxygen saturation ("SpO_2"), blood glucose, total hemoglobin ("SbHb"), methemoglobin (SbMet"), carboxyhemoglobin ("SpCO"), bulk tissue property measurements, water content, pH, blood pressure, respiration related information, cardiac information, indications of perfusion ("PI"), pleth variability indices ("PVI"), or the like. In some embodiments, sensor data can provide information regarding physiological parameters such as EEG, ECG, acoustic respiration rate ("RRa"), end-tidal carbon dioxide ("$EtCO_2$"), return of spontaneous circulation ("ROSC"), or the like.

The sensor data can be corrupted by noise due to patient movement, electromagnetic interference, or ambient light. Therefore, the sensor data is transmitted from sensor **110**

along the first cable **120** to the processing module **130**, which can apply noise filtering and signal processing techniques described below to provide output data for display on the smartphone **160**. Such complex processing techniques can exceed the processing capabilities of the smartphone **160**, and therefore the processing module **130** drives operation of the sensor **110** and handles signal processing and transmits the processed sensor parameter data as output measurement data. Smartphone **160** can be coupled to the processing module **130** by a second cable **140** and connection port **150**, in some embodiments, and in other embodiments can be configured to wirelessly transmit the parameter data to the smartphone **160** or another computing device.

Smartphone **160** can include a display screen such as an LED or LCD screen, and can include touch sensitive technologies in combination with the display screen. Smartphone **160** can include software configured to display some or all of the output measurement data on the display screen. The data display can include numerical or graphical representations of blood oxygen saturation, heart rate, and/or a plethysmographic waveform, and some embodiments can simultaneously display numerical and graphical data representations.

The smartphone **160** can include software such as an application configured to manage output measurement data from the processing module **130**. The application functionality can include trend analysis, current measurement information, alarms associated with above/below threshold readings, reminders to take measurement data at certain times or cycles, display customization, iconic data such as hearts beating, color coordination, bar graphs, gas bars, charts, graphs, or the like, all usable by a caregiver or smartphone user to enable helpful and directed medical monitoring of specified physiological parameters. The smartphone **160** can also include network connection capabilities such as one or more of a cellular network, satellite network, Bluetooth, ZigBee, wireless network connection such as Wi-Fi, and a wired network connection.

In some embodiments, software capable of analyzing the output measurement data received from the processing module **130** and making the data available in an appropriate manner for health management is installed on the smartphone **160**. In some embodiments, the smartphone **160** includes software which allows a user to view the data in a multitude of ways. For example, in some embodiments a user can be able to view the raw data received from the sensor **110**. In other embodiments, a user can be able to select from a plurality of graphical representations of the data (e.g., bar graphs, charts, etc). In other embodiments, the user can be able to manipulate the data to visualize trends in the data. The smartphone **160** can also be able to alert the user and/or a physician or other care provider to an abnormal data reading. For example, an abnormally low or high blood oxygen saturation reading can cause the smartphone **160** to buzz, vibrate or otherwise notify the user of an abnormal reading, or to transmit a notification to a physician via a network.

The smartphone **160** can have the capability of sending physiological data to a computer (e.g., a home computer) on which the user manages his health data. The data can also be sent to a physician or pharmacist for their expertise and feedback. The smartphone **160** and the computing device to which data is being sent can be connected directly or via a network such as a LAN, WAN or the Internet. The connection can be wired or wireless. Other connection configurations are also possible.

The system **100** as illustrated in FIG. **1**C shows an exploded view of the processing module **130** and the connection port **150** to reveal the components thereof. The processing module **130** drives operation of the sensor **110** and receives raw detected signals from the sensor **110**. The processing module **130** processes the raw detected signals to determine a physiological measurement. The processing module **130**, in some embodiments, employs advanced signal processing techniques, including parallel engines and adaptive filters, to allow accurate monitoring of arterial oxygen saturation and pulse rate even during the most challenging conditions. In some embodiments, the processing module **130** can employ Signal Extraction Technology, or Masimo SET®, using parallel signal processing engines to separate the arterial signal from sources of noise (including the venous signal) to measure SpO_2 and pulse rate accurately, even during motion. The processing module **130** can filter raw physiological sensor data input from the sensor **110**, and the processing module **130** can provide filtered physiological parameter data to the mobile computing device for display or storage.

One drawback of implementing physiological measurement technology on mobile computing devices is the processing overhead typically required for recognizing parameters from data input by the sensor by filtering such raw physiological measurement data. Processing overhead measures the total amount of work the central processing unit (CPU) of the device can perform and the percentage of that total capacity which is used by individual computing tasks, such as filtering raw physiological measurement data. In total, these tasks must require less than the processor's overall capacity. Moreover, complicated software required to process raw signals and determine physiological measurements can be stored in the processing module **130** in a separate memory unit separate from the mobile device. This frees up memory available to the mobile device.

The current generation of mobile processors is not well adapted to deal with the complexity and corresponding processing overhead of filtering raw physiological measurement data, especially in conjunction with the many other common high performance uses of mobile devices. As an example, the mobile device processor may be used to run a mobile physiological monitoring application concurrently with receiving sensor data, among other applications selected by the user. Many common mobile applications such as maps, games, email clients, web browsers, etc., are typically open on a user's smartphone. During physiological monitoring, a substantially constant stream of data can be sent from the sensor to the mobile device. Accordingly, if the mobile CPU is required to filter the raw data, device performance can be impaired and the user can experience significant latency in the use of other applications. If the data filtering overhead exceeds the overall processing capacity of the CPU then the mobile device would be incapable of processing the data, and the user can experience serious technical problems as a result.

Overload of the CPU can significantly increase system power consumption. To mitigate the possibility of CPU overload, a larger processor can be provided. However, increasing the size of the mobile processor core or cache would deliver performance increases only up to a certain level, beyond which heat dissipation issues would make any further increase in core and cache size impractical. Additionally, overall processing capacity is further limited by the smaller size of many mobile devices, which limits the number of processors that can be included in the device.

Because mobile computing devices are generally battery-powered, high performance uses also shortens battery life.

By providing a separate processing module **130** to mediate the data flow from the sensor **110** to the mobile device **160**, the complex signal processing required for generating recognizable physiological parameters from raw sensor data can be handled by the processing module **130** and not the mobile CPU. Moving the signal processing calculations away from the mobile CPU frees it up for important core tasks as well as processing of mobile applications. Further, optimizing the mobile CPU can directly correlate with increased battery life, even considering the power draw of the processing module **130** on the mobile device battery. Accordingly, incorporation of a processing module **130** into a mobile sensor cable can be beneficial for conserving processing of the mobile CPU and for reducing battery demands across the system **100**.

Coupled to cable **120** is an information element **133**. The information element **133** could be provided through an active circuit such as a transistor network, memory chip, EEPROM (electronically erasable programmable read-only memory), EPROM (erasable programmable read-only memory), or other identification device, such as multi-contact single wire memory devices or other devices, or the like.

The processing module **130** includes a lower shell **131**, an enclosure with bend relief **132**, processing board **134**, and an upper shell **135**. The enclosure **132**, upper shell **135**, and lower shell **131** surround the processing board **134** and can protect the sensitive circuitry of the board **134** from damage. In such an embodiment, processing board **134** is the portion of the module **130** that communicates with the first cable **120** and sensor **110**, as well as with the second cable **140** and mobile computing device. In an embodiment, the board **134** can access information stored on the information element **133** of the first cable **120**.

In an embodiment, the processing module **130** is located in a middle portion of the cable, away from either the sensor **110** or the connection port **150**. The processing module **130** can be located a first distance from, and mechanically isolated from, the sensor, so as not to interfere with the placement of the sensor on a measurement site of a user's body. This placement prevents the sensor from being encumbered by the processing module **130** and interfering with placement and use of the sensor. Thus, the sensor is also kept relatively lightweight for ease of use. The processing module **130** can be located a first distance from, and mechanically isolated from, the connection port **150**, so as not to interfere with the ability of the connection port **150** to secure to a user's mobile device. This allows the connection port **150** to be unencumbered by the bulk and weight of the processing module **130** which could interfere with the connection to the user's mobile device. In some embodiments, the second distance can be smaller than the first distance, placing the processing module **130** closer to the connection port **150** than to the sensor **110**. This prevents the weight of the processing module **130** from interfering with or pulling on the sensor **110**. In an embodiment, the components of the processing module **130** are constructed from lightweight materials in order to avoid pulling the sensor **110** off of a user or disconnecting the connection port **150** from a mobile device.

The processing module **130** and sensor **110** draw power for operation from the mobile computing device for operation. This frees the processing module **130** from needing a separate power source. Also, although a display screen can be included on the processing module **130**, no separate display screen is necessary as the measurements are displayed on the user's mobile device.

The enclosure **132** can have a bend relief portion **138** on either side. The bend relief portions **138** may enhance the electrical and mechanical integrity and overall performance of the cable assembly by providing a gradual transition from the flexible cables to substantially rigid connection points with the processing board **134** contained within the enclosure. The bend relief portions **138** can prevent mechanical force, such as an axial load or flexing, that is applied to the exterior of either cable **120**,**140** from being transferred to the electrical terminations with the processing board **134**. The bend relief portions **138** can be premolded and formed with the body of the enclosure, and in some embodiments a crimp ring may be secured around the cable within each bend relief.

The enclosure **132** can be formed, in some embodiments, by a flexible plastic or rubber material. Suitable materials can include thermoplastic rubbers such as Santoprene®. The upper and lower shells **135**, **131** can be formed from a hard plastic material. Suitable materials can include thermoplastic polymers. For example, in an embodiment the upper and lower shells **135**, **131** can be formed from a blend of two or more of polycarbonate (PC), polyethylene terephthalate (PET), polybutylene terephthalate (PBT), or another polyester, such as Bayer Makroblend® UT5207. In another embodiment, the upper and lower shells **135**, **131** can be formed from a resin, for example a blend of semi-crystalline polyester (typically PET or PBT) and PC, such as XENOY™ Resin 6620U. The material for the upper and lower shells **135**, **131** can be selected for having desirable impact resistance, toughness, and heat resistance. The upper and lower shells **135**, **131** can be formed from the same or different materials.

The body portion of the enclosure **132** can be formed as a gasket which can seal between the upper shell **135** and lower shell **131** and form a substantially water-tight seal, in order to protect the processing board **134** from moisture. In some embodiments, the upper and lower shells **135**, **131** can be formed to fit together with the enclosure **132** in a substantially water-tight manner. In an embodiment, the upper and lower shells **135**, **131** can be sealed to the enclosure **132** using epoxy around the perimeter of each shell, and/or on mounting posts located on the shell or the enclosure. In some embodiments, the cable entry areas of each bend relief portion **138** of the enclosure **132** can also be filled with epoxy to form a substantially sealed enclosure for the processing board **134**.

The cables **120**, **140** can be constructed with a Kevlar fiber core for strength and durability, in some embodiments. The Kevlar fiber core can be bundled in the center of a plurality of signal lines, for example five signal lines. The signal lines can be tinned copper jacketed with polypropylene (PP). The bundle of signal lines can be encased in a braided outer shield, for example a tinned copper outer shield with approximately 95% minimum coverage of the bundled signal lines. The outer shield may be encased, in turn, by a multi-layer Teflon film or wrap, in some embodiments, to form a low-friction separator and barrier from an outer jacket. The cables **120**, **140** can be further protected by a medical grade PVC outer jacket, or an outer jacket constructed from another biocompatible, flexible plastic or rubber material. Other configurations for the cables **120**, **140** are possible. The cables can be designed to have a minimum pull strength of 75 kg, or approximately 75 kg, in some embodiments.

As illustrated, some embodiments can optionally include a second processing board **136**. For example, the first processing board **134** can be a digital processing board and the second processing board **136** can be an analog processing board. The analog and digital processing boards may perform separate processing functions. In some embodiments, wires from the first cable **120** can be connected to the analog processing board **136**, and wires from the second cable **140** can be connected to the digital processing board **136**. In some embodiments, the digital processing board can be in communication with the first information element **133**. The first information element **133** can be an EPROM or EEPROM device. The analog processing board can be in communication with a second information element **137** coupled to cable **120**. The second information element **127** can be a resistor, in some embodiments, for example an ArCal or ProCal resistor. A resistance value of the resistor can be indicative of a wavelength of light used in an oximetry sensor **110** coupled to the cable **120**, and the resistor can be coupled in parallel with the sensor.

In one embodiment, the processing board or boards can include one of many OEM boards commercially available from Masimo which process incoming intensity signals responsive to an amount of attenuation of light in pulsing patient blood and which determine output measurements for a wide variety of physiological parameters from the processing. The processing board **134** can include the MS-2040 OEM board available from Masimo, which can measure Masimo optical SET measurements such as oxygen saturation (SpO_2), pulse rate, perfusion index (PI), signal quality (SIQ), optionally pleth variability index (PVI), and the like. The physiological monitoring system **100** can also include, in addition to or instead of the MS-2040 OEM board, other processing boards available from Masimo. For example, the physiological monitoring system **100** can include the MX-5 board available from Masimo, which has variable power consumption based on which parameters are being acquired and displayed. The MX-5 board can measure the Masimo SET parameters described above plus optional Rainbow® parameters including: hemoglobin (SpHb), oxygen content (SpOC), carboxyhemoglobin (SpCO), methemoglobin (SpMet), and acoustic respiration rate (RRa) (among possibly others). The addition of the acoustic respiration rate can result in the display of the physiological monitoring system **100** outputting a second waveform (e.g., an acoustic respiration waveform).

The board **134** can include a signal processing system. Embodiments of the signal processing system can employ a noise filtering system configured to filter the data obtained during pulse oximetry measurements using red and infrared light, as such data is often contaminated due to motion. Identification and removal of these motion artifacts is often a prerequisite to any signal processing used to obtain blood oxygen saturation, pulse rate, or other physiological data. The signal processing system can provide the desired parameters as outputs for a display. Outputs for display are, for example, blood oxygen saturation, heart rate, and a clean plethysmographic waveform. Complex operations such as noise filtering and signal processing can require specialized processing or significant computational overhead, such that a typical user mobile device can not have sufficient processing power. Accordingly, the processing module **130** can perform signal processing on raw data received from the sensor and can provide physiological parameters as an output to a display and/or storage device.

The connection port **150** includes shell **151**, bend relief **152**, connector **153**, and cap **154**. Bend relief **152** is an important feature of a medical cable assembly for both the electrical and mechanical integrity and performance of the second cable **140**. The connection port **150** is typically rigid, and the bend relief **152** provides a transition from the stiffness of the connection port **150** to the flexibility of the second cable **140**. Preferably, bend relief **152** will prevent mechanical force applied to the exterior of the cable from being transferred to the electrical terminations within the connector, which could lead to failure.

Shell **151** generally encloses connector **153** and can be matable with cap **154** to provide added protection for the connector **153**. Connector **153** can be shaped to physically and electrically connect with a specific device. Connection port **150** can be one of many different types of ports. For example, connection port **150** can be a device-specific port such as an iPhone port or another smartphone port, a USB port, an Ethernet port for connection to a wired network, a serial port (e.g., RS232), a video out port which allows projection of the device screen on a larger display, combinations of the same, or the like. Further, the connection port **150** can be equipped with one or more wireless interfaces (such as WiFi, Bluetooth, Zigbee, or the like).

FIG. **2** illustrates a block diagram of an example physiological monitoring system **200**. As illustrated, the system **200** includes a cable **230** and a mobile device **220**. The cable **230** includes a sensor **202**, which can be any of the physiological sensors described above with respect to FIGS. **1**A, **1**B, and **1**C, and a signal processing module **210**. The mobile device **220** can provide power **206** to the signal processing module **210** and the sensor **202**. The sensor **210** can transmit raw data **204** to the signal processing module **210**, and the signal processing module can convert the raw data **204** into data representing physiological parameters **226** for transmission to the mobile device **220**.

The mobile device **220** can be any of the portable computing devices discussed above, such as a smartphone, laptop, tablet, or the like. The mobile device **220** can include a display **222** for display of the parameters, for example in a user interface and/or software application, as discussed in more detail below. The display **222** can include a display screen such as an LED or LCD screen, and can include touch sensitive technologies in combination with the display screen. The mobile device **220** can also include storage **224**, which can be configured for storage of parameters **226** and parameter history data and/or software applications for managing the data and sensor **110**. In some embodiments, the storage **224** can be physical storage of the device **220**, and in some embodiments the storage **224** can be remote storage, such as on a server or servers of a data hosting service. The mobile device **220** can also include a network connectivity feature **228** such as Bluetooth, satellite network capability, mobile communications capability, Wi-Fi, or the like. In some embodiments the mobile device **220** can also include a data transfer port.

The signal processing module **210** can be configured to receive raw sensor data **204** from the sensor **202**, and to process the raw data **204** into identifiable parameters **226** for display and/or storage by the mobile device **220**. In some embodiments, the mobile device **220** can not have sufficient processing power to handle the conversion of raw data **204** to identifiable parameters **226**. For example, in the context of pulse oximetry, the signal processing module **210** can use adaptive filter technology to separate an arterial signal, detected by a pulse oximeter sensor, from the non-arterial noise (e.g. venous blood movement during motion). During routine patient motions (shivering, waving, tapping, etc.), the resulting noise can be quite substantial and can easily

overwhelm a conventional ratio based oximetry system. This can provide accurate blood oxygenation measurements even during patient motion, low perfusion, intense ambient light, and electrocautery interference. Accordingly, false alarms can be substantially eliminated without sacrificing true alarms.

The signal processing module **210** can include a noise filter engine **212**. In some embodiments, the noise filter engine **212** can perform a discrete saturation transform process to substantially remove noise from the raw sensor data **204**. The discrete saturation transform process outputs a maximum power as an SpO_2 percentage. For example, the discrete saturation transform process can build a noise reference signal from incoming red and infrared signals of a pulse oximeter sensor, in some embodiments, for each percent SpO_2, from 1 to 100 percent. The noise reference signal can be passed through an adaptive filter which can cancel correlated frequencies between the reference signal and the incoming infrared signal. If the frequencies between the two inputs are all similar, the entire signal can be canceled, and a low energy output occurs. If the frequencies between the two inputs are dissimilar, a minimal amount of signal cancels and a high-energy output can be obtained. The energy output from the adaptive filter can be measured and plotted for all possible saturations from 1 to 100 percent, for example in 0.5 percent increments every 0.4 seconds, in some embodiments. During measurements in which the user exhibits no motion, a discrete cosine transfer algorithm can generate one energy output peak, and several output peaks can be generated during motion. Because arterial blood has the highest oxygen saturation, a peak picker process can select the highest saturation peak as the percent SpO_2.

In some embodiments, the noise filter engine **212** can employ a plurality of adaptive filter processes in parallel to separate the physiological signal from the noise, and can leverage the unique strengths of each adaptive filter processes to obtain accurate readings through various patient conditions. For example, in one embodiment of pulse oximetry measurements, parallel adaptive filters can include a discrete saturation transform, sinusoidal saturation transform, and fast saturation transform, as well as possibly others. A sinusoidal saturation transform can be a time domain transform that defines a window around a derived pulse rate estimate, subtracts a preselected set of frequencies to find a minima, and can use the minima to determine the location of the maximum power and thus the true pulse rate. A fast saturation transform may include, in some embodiments, a spectral or Fourier transform, a spectral analysis, and identification of physiological parameters through frequency, magnitude, or other aspects of the spectral analysis. In one embodiment, demodulation and decimation of the raw sensor data **204** may occur prior to the fast saturation transform.

The noise filter engine **212** can optionally include an arbitration module **214** in embodiments where multiple calculation engines are used. In some embodiments, the arbitration module **214** may be a confidence-based arbitrator. The arbitration module **214** can include instructions to compare the output of each adaptive filter process in order to generate a final determination of the denoised physiological signal. The arbitration module **214** can also arbitrate physiological measurements based on any number of parameters, for example a highest confidence level or whether a threshold confidence level was reached. Furthermore, the arbitration module **214** can arbitrate based on expected values, previous values, averages or the like. Post processor **216** can apply additional signal conditioning techniques to the output of the arbitration module **214** in order to output parameter data **226** to the mobile device **220**.

II. Example Computing Environment

FIG. **3** illustrates an embodiment of a computing environment **300** in which a mobile patient monitoring device **330** can communicate with various computing devices and services over a network **305**. Although various devices and services are illustrated, in some embodiments the mobile patient monitoring device **330** can be configured to communicate with a subset of the illustrated devices and services, and in some embodiments can be configured to communicate with only one of the illustrated devices and services.

In an embodiment, the mobile patient monitoring device **330** can communicate over a network **305** with calibration service **310** over the network **305**. The example network **305** shown can be a local area network (LAN), wide area network (WAN), the Internet, an intranet, cellular communications network, satellite communications network, or combinations of the same or the like. The calibration service **310** can accumulate and aggregate received physiological measurement data as calibration data **314** to generate more accurate parameter values. Calibration data for physiological sensors such as pulse oximeters is typically calculated over a patient sample from a clinical study. The clinically generated calibration data can be supplemented, in some embodiments, by the calibration data **314** gathered from physiological sensors **330**. Advantageously, gathering measurement data from a number of mobile physiological sensors **330** can expand such a data set significantly and lead to higher accuracies and/or new discoveries regarding parameter measurement. The calibration data **314** can be stored anonymously or in other manners which are compliant with privacy laws regarding medical data. In some embodiments, non-identifying demographic information can advantageously be associated with the calibration data **314**.

The calibration service **310** can include a calibration module **312** configured with instructions to calculate a best fit function for the population data **316** within the calibration data **314**. The best fit function can be used to generate a calibration curve associating sensor reading values with parameter values. The best fit function can be transmitted to connected patient devices **330** in order to associate sensor readings with more accurate parameter values. Specifically, false positives can be reduced, variances in SpO_2 can be detected and filtered, and/or measurement confidence can be evaluated, among other advantages. Calibration data **314** can also include individual data **318**, for example individual variations from the expected sensor reading to parameter value relationship defined by the best fit function. Methods of using a single sensor to improve calibration data which can be implemented by the disclosed systems are disclosed in U.S. patent application Ser. No. 13/733,782, titled "AUTOMATED CCHD SCREENING AND DETECTION," filed Jan. 3, 2013, the entirety of which is hereby incorporated by reference.

In an embodiment, the mobile patient monitoring devices **330** can communicate with home/mobile clinician devices **320** over the network **305**. Any type of clinician computing device **330** can communicate with mobile patient monitoring device **330** including, for example, laptops, desktops, servers, work stations, tablets, wireless handheld devices such as cell phones, smart phones, personal digital assistants and wireless pagers, combinations of the same or the like. Alternatively or additionally, the mobile patient monitoring

devices **330** can communicate with patient databases of hospitals and other care facilities **225** over the network **305**. The mobile patient monitoring device **330** can output parameter data, trend data and/or alarms to the home/mobile clinician devices **320** and/or hospitals and other care facilities **225**.

III. Example Software Applications

FIGS. **4**A-**4**D illustrate various embodiments of applications for display and management of physiological monitoring data. Such applications can be available for download or installation on a user device from a provider of the physiological sensors described herein, for example from the provider's web site, or through a mobile store application. In an embodiment, a mobile physiological monitoring software application can be initialized when a user connects a sensor cable to their mobile device. The user interface examples illustrated in FIGS. **4**A-**4**D are provided to illustrate and not to limit the capabilities of such applications.

Some embodiments of the software application can be used with the smartphone **160** of FIGS. **1**A, **1**B, and **1**C, though any mobile user device can be used in other embodiments. As illustrated in FIG. **4**A, smartphone **160** includes a display **410**, which can be used to generate a user interface for the software application. The application can include a plurality of display portions in which a plurality of physiological parameters can be displayed, such as SpO_2 display **420**, heart rate display **430**, perfusion index display **450**, or plethysmographic waveform display **450**. Any combination of the physiological parameters disclosed herein can be displayed on the smartphone **160**. The configuration of these various display portions is meant for illustrative purposes, and one skilled in the art would appreciate that the parameter displays could be rearranged relative to one another, displayed alone, or the user interface could be modified to include other parameter display portions. Another example of a variety of display portions is illustrated in FIG. **4**B. Further, although some of the parameter display portions employ numerical representations of the physiological data, some embodiments can employ graphical representations, for example a beating heart can indicate heart rate.

The user interface can also include an options display portion **460** which allows the user to interact with his physiological monitoring data in a variety of ways. For example, the user can choose to view trends in the data, as illustrated in FIG. **4**C, or to change the manner in which the data is represented such as by viewing a histogram or other graph. The user can be also able to view the history of his physiological measurement data. In some embodiments, history or trend data can be displayed with a start date and/or time and an end date and/or time, and the user can be able to adjust the window of data displayed. For example, on a touch sensitive interface the user can narrow or expand a window of trend data using a pinch gesture with two fingers. The user can also be able to export a selected amount of trend or history data, such as by electronic mail, through a medical service, or as a spreadsheet, to name a few examples. A settings option can be displayed which would allow the user to modify other aspects of the program, and can also enable the user to set alarms or reminders to take future measurements.

Turning to FIG. **4**D, an example instruction user interface is shown which can be presented to a user upon initialization of the application. The instruction interface can include graphical and numbered steps to guide the user through set up of the sensor, and can include a user selectable option to start tracking physiological parameter measurements.

In certain embodiments, the application can be downloadable from a computer network at a cost, by subscription, pay-per-use, or the like. Other embodiments can advantageously incorporated caregiver-specific applications which include reminders for timed measurements or protocols. For example, a caregiver for a pre-surgical patient can desire measurement data for a certain minimum time per minimum period (20 min per every hour) or the like to have sufficient data to make diagnosis or decisions for treatment. A caregiver-specific application can be advantageously programmed to accomplish such a protocol. Moreover, signal quality or confidence indicators such as perfusion index ("PI") or signal IQ ("SIQ") can be used to ensure data meets certain minimum confidence and/or signal-to-noise limitations. Thus, the application can implement the protocol and extend or add measurement intervals to ensure minimum signal quality standards are met. Other caregiver-specific applications can provide animated or textual instructions, links to online information regarding certain monitoring situations, ailments, or other useful patient research.

In an embodiment, data acquired through the application can be uploaded to caregiver or device provider systems to increase the population data and used to improve signal processing. In a preferred embodiment, issues of privacy and compliance with governmental regulations are strictly enforced through the application logic. In some embodiments, non-identifying demographic information can advantageously be associated with such data. Moreover, password and/or additional authentication requirements can be required to access stored data in the application, such as, for example, fingerprint technologies, facial recognition technologies employing the smartphone's camera, voice recognition technologies employing the smartphone's audio transducer, or the like can further assist in meeting privacy concerns.

IV. Overview of Compatible Sensor Embodiments

As illustrated in FIG. **5**A, a physiological sensor **520** can be an electroencephalograph ("EEG") configured for measurement of electrical activity along the scalp. Such mobile EEG systems can be used, for example, in detecting and monitoring epileptic activity. EEG systems can also be used for diagnosis and management of sleep disorders or for studies of sleep. Electroencephalography is used extensively in neuroscience, cognitive science, cognitive psychology, neurolinguistics and psychophysiological research. In many of these contexts, a sensor **520** compatible with a common mobile computing device of a user would provide advantages such as convenience and affordability. In some embodiments, the sensor **520** can be SEDLine®, available from Masimo. SEDLine® brain function monitoring can use four channels of information, in some embodiments, to monitor both sides of the brain's electrical activity.

Turning to FIG. **5**B, a capnometer or capnograph **530** can be configured for mobile physiological parameter measurement. Such sensors **530** can be designed for the measurement of CO2, N2O, and anesthetic agents, among others. Capnography can be useful for metabolic measurements and nutritional assessment, and accordingly a mobile sensor **530** can provide increased accessibility for such uses.

An acoustic respiratory monitor **540**, as shown in FIG. **5**C, can also be configured for mobile physiological parameter measurement. An acoustic respiratory monitor **540** can measure respiration rate using an adhesive sensor with an

integrated acoustic transducer that can be comfortably applied to the patient's neck. Continuous monitoring of respiration rate can be important for post-surgical patients receiving patient-controlled analgesia for pain management, as the sedation can induce respiratory depression and place patients at considerable risk of serious injury or death. Accordingly, a mobile respiratory monitor **540** can be desirable for convenient and continuous monitoring of such patients, among other reasons.

V. Overview of Example Mobile Physiological Monitoring Processes

FIG. **6** illustrates an embodiment of a pre-anesthesia monitoring process **600**. The process can be implemented by the physiological monitoring system **100** of FIGS. **1**A, **1**B, and **1**C, in some embodiments.

The process **600** can begin at block **605** in which a care provider recommends a medical procedure requiring anesthesia for a patient. Certain medical conditions can present safety concerns for the patient during anesthesia, so at block **610** the patient can be provided with a portable monitoring system including a sensor connectable to one of the patient's personal mobile computing devices. In some embodiments the patient can be provided with multiple sensors and/or a software application for collection and management of physiological data.

At block **615**, the portable monitoring system can collect and store physiological data from the patient. Optionally, at block **620**, the collected data is analyzed for risk factors indicating a medical condition with implications for anesthesia, such as obstructive sleep apnea. At block **625**, the collected data and/or analysis of the data is provided to the patient's physician or another care provider. In some embodiments, a physician can conduct the analysis after receiving the patient's data.

At decision block **630**, a determination is made regarding whether the data analysis indicates that sleep apnea or another medical condition impacting the safety of anesthesia is present. If such a condition is present in the data, then the process **600** moves to block **645** in which the anesthesiologist is alerted. At step **650**, a patient treatment strategy is developed that addresses the possible complications of the patient undergoing anesthesia with the detected condition. If no safety-impairing medical condition is present in the data, then the process **600** moves to block **640** in which the patient's physician can elect to proceed with the recommended medical procedure and anesthesia.

FIG. **7** illustrates an embodiment of a continuum of care process **700**. The process **700** can be implemented, in some embodiments, by the computing environment **300** of FIG. **3**. In an embodiment, the process **600** can be implemented at least in part by the network **305** to facilitate continued patient monitoring when a patient leaves a hospital or other facility.

At block **705**, monitoring data of a patient is received at a clinical facility, for example by a networked medical service which can receive and store patient monitoring data, among other features. Once the patient is discharged, at block **710** the patient can be outfitted with a portable monitoring system. The portable monitoring system can monitor the same parameters as a device used to monitor the patient in the clinical facility. In addition, the portable monitoring system may, for instance, be any of the sensors and processing cable components, or variations thereof, described herein.

When a patient is discharged, there is a typically a period of time where the patient is not being monitored once the patient leaves the facility. However, the continuum of care process **700** employing mobile physiological sensors can facilitate continued monitoring of the patient, for example during travel between the facility and the patient's residence or when the patient arrives at home, by receiving monitoring data from the patient via a cellular or satellite network at block **715**. An activity level of the patient, for example resting or walking, can be monitored at block **620** in order to set the appropriate thresholds for determining when physiological parameters indicating an alarm condition are occurring at block **725**. The patient's activity level can be monitored by the device, in some embodiments, or can be input by the patient or a care giver.

Periodically, the mobile physiological sensor system can recheck the patient's activity level at block **730** to determine whether the activity level has changed. If the patient's activity level has changed, then the process **700** loops back to block **725** to adjust alarm settings for the patient's physiological data based on the activity level. If the patient's activity level has not changed, then the process **700** can move to block **735** in which it is determined whether an alarm condition is occurring based on the patient's physiological parameters and the alarm settings. A software application installed on the patient's mobile device can be configured to detect the alarm condition. If an alarm condition is not occurring, then the process **700** loops back to block **715** in which the mobile physiological sensor continues to perform physiological measurements and transmit the measurements to the mobile device through a signal conditioning processor. If an alarm condition is detected at block **735**, then the patient's mobile device can pass a notification to a care provider via a network connection. Accordingly, the mobile physiological sensor system can facilitate a continuum of care for a patient and continuous monitoring even when a patient has left a clinical facility.

FIG. **8** illustrates an embodiment of a mobile physiological data monitoring process **800**. The process can be implemented, in some embodiments, by the physiological monitoring system **100** of FIGS. **1**A, **1**B, and **1**C, or the physiological monitoring system **200** of FIG. **2**.

At block **805**, a portable user monitoring system is provided including physiological sensor, processing module, and device connection port. The physiological sensor can be any of the sensor examples discussed herein. The processing module can be the processing module **130** described in FIGS. **1**A, **1**B, and **1**C or the signal processing module **210** of FIG. **2**. The processing module can implement Masimo SET technology, in some embodiments. The device connection port can be configured for use with a standard personal computing device, such as a smartphone, and can be connected to the processing module physically via a cable or wirelessly.

At block **810**, the user's mobile computing device, while connected to the portable patient monitoring system, provides power to the sensor and processing module. Accordingly, the sensor and processing module can be configured in some embodiments so as to draw only minimal power from the mobile computing device, as such devices are typically powered by batteries.

At block **815**, the processing module receives raw physiological sensor data from the sensor. The processing module performs signal conditioning on the raw data at block **820**, for example any of the signal conditioning techniques described herein, to remove noise from the raw data and obtain physiological parameter data. At block **825**, the

processing module outputs the physiological parameter data to the user's mobile computing device for display and/or storage on the device. Accordingly, a user can conveniently conduct physiological measurements and be presented with physiological data on their mobile device in a wide variety of contexts.

FIG. **9** illustrates an embodiment of a user-guided monitoring process **900**, which can be carried out by a user on their personal computing device without the need for physician or caregiver aid. The process **900** can be carried out by a mobile physiological monitoring application, as discussed above, in conjunction with a mobile physiological sensor. The physiological sensor can be any of the sensor examples discussed herein.

At block **905**, the user is instructed to insert the connection port of a cable including a physiological sensor and a processor into a corresponding port on their mobile computing device, and at block **910** the user is instructed to place the sensor at a measurement site. In some embodiments, these blocks can be implemented by an instruction user interface such as is depicted in FIG. **4**D and discussed above.

At block **915**, the mobile device receives measurement data, which can be raw sensor data that has been processed by a processing module prior to being sent to the mobile device. At block **920**, the mobile physiological monitoring application can determine based on the measurement data whether an error is occurring. If it is determined that an error is not occurring, then the mobile device can continue to receive measurement data at block **915**. If it is determined that an error is occurring, then the mobile physiological monitoring application can determine a potential or likely error source at block **925**.

Based on the determined error source, the mobile physiological monitoring application may, at block **930**, display a message to aid the user to aid in resolution of the error. Example messages include "Ensure cable is connected," "Sensor not working." "Place sensor on properly," "Searching for pulse," "Interference detected, see manual," "Low perfusion, see manual," "Too much surrounding light," "Low signal quality, see manual," and "Connecting, please wait," among others. In some embodiments an audible or visual indication can also be provided to alert the user to the presence of the error. At block **935**, the mobile physiological monitoring application can determine whether the user has resolved the error. The mobile physiological monitoring application can repeat this action at predetermined intervals until the error is resolved or the application is terminated by the user, in some embodiments. In other embodiments, the mobile physiological monitoring application can determine whether the error has been resolved based on a change in received measurement data values. If, after a predetermined threshold of time, the error is not resolved, then the process **900** ends. If the error is resolved, the process **900** loops back to block **915**, and the mobile device can continue to receive measurement data.

FIG. **10** illustrates an embodiment of a data-logging process **1000**. The data-logging process **1000** can run continuously or periodically during operation of a mobile physiological monitoring application, as discussed above.

At block **1005**, the mobile physiological monitoring application can receive measurement data, which can be raw sensor data that has been processed by a processing module prior to being sent to a mobile device. This data is stored, at block **101**, in a user history, for example in storage of the mobile device or in a networked data storage service. At block **1015**, the mobile physiological monitoring application determines that a user has requested to be presented with history data, and accordingly outputs at least some of the stored data for display to the user at block **1020**. In some embodiments, the user can specify a desired range of stored history data when making the request. In other embodiments, the device can output a predetermined range of the history data, for example based on a recent time window of the data or patterns in the data.

At block **1025**, the mobile physiological monitoring application can dynamically adjust the amount of displayed data based on user input. This step can be optional based on whether a user provides input regarding adjusting the data. In some embodiments, the user can be able to specify particular physiological parameters to add or remove from the display. In an embodiment implemented on a touch-sensitive display, a user can use a two-finger pinching gesture to change the range of the time window of the data, or can use a swiping motion to move forwards or backwards through the data. Such adjustments can be implemented using other user interface elements on non-touch sensitive displays. A user can also be able to select from a variety of possible representations of the data, such as a chart, graph, plot, or other graphical representation as well as numerical representations such as spreadsheets, in some embodiments.

At block **1030**, the mobile physiological monitoring application can receive a user request to export the stored history data. If no such request is received, then the mobile physiological monitoring application can loop back to block **1005** and continue to receive physiological measurement data. If the user requests to export the data, then at block **1035** the mobile physiological monitoring application can export a subset of the stored history data according to user format specification. For example, the user can specify a time and/or date range of data to export, can select a format (such as a spreadsheet or a graph), and can select an exporting means such as email or direct transmission to a physician or networked medical service.

At block **1040**, the user can be presented with an option to delete the stored history data. In some embodiments, the user can be asked whether to delete data that has been exported. If the user does not want to delete the data, then the mobile physiological monitoring application can loop back to block **1005** and continue to receive physiological measurement data. If the user requests to delete the data, then the mobile physiological monitoring application can clear stored history data according to user instructions, and can then loop back to block **1005** and continue to receive physiological measurement data.

VI. Terminology

Although many of the examples discussed herein are in the context of pulse oximetry, this is for illustrative purposes only. The sensors, signal conditioning techniques, and mobile applications discussed herein can be adapted for other physiological parameters or for multiple physiological parameters.

Many other variations than those described herein will be apparent from this disclosure. For example, depending on the embodiment, certain acts, events, or functions of any of the algorithms described herein can be performed in a different sequence, can be added, merged, or left out all together (e.g., not all described acts or events are necessary for the practice of the algorithms). Moreover, in certain embodiments, acts or events can be performed concurrently, e.g., through multi-threaded processing, interrupt processing, or multiple processors or processor cores or on other parallel architectures, rather than sequentially. In addition,

different tasks or processes can be performed by different machines and/or computing systems that can function together.

The various illustrative logical blocks, modules, and algorithm steps described in connection with the embodiments disclosed herein can be implemented as electronic hardware, computer software, or combinations of both. To clearly illustrate this interchangeability of hardware and software, various illustrative components, blocks, modules, and steps have been described above generally in terms of their functionality. Whether such functionality is implemented as hardware or software depends upon the particular application and design constraints imposed on the overall system. The described functionality can be implemented in varying ways for each particular application, but such implementation decisions should not be interpreted as causing a departure from the scope of the disclosure.

The various illustrative logical blocks and modules described in connection with the embodiments disclosed herein can be implemented or performed by a machine, such as a general purpose processor, a digital signal processor (DSP), an application specific integrated circuit (ASIC), a field programmable gate array (FPGA) or other programmable logic device, discrete gate or transistor logic, discrete hardware components, or any combination thereof designed to perform the functions described herein. A general purpose processor can be a microprocessor, but in the alternative, the processor can be a controller, microcontroller, or state machine, combinations of the same, or the like. A processor can also be implemented as a combination of computing devices, e.g., a combination of a DSP and a microprocessor, a plurality of microprocessors, one or more microprocessors in conjunction with a DSP core, or any other such configuration. Although described herein primarily with respect to digital technology, a processor can also include primarily analog components. For example, any of the signal processing algorithms described herein can be implemented in analog circuitry. A computing environment can include any type of computer system, including, but not limited to, a computer system based on a microprocessor, a mainframe computer, a digital signal processor, a portable computing device, a personal organizer, a device controller, and a computational engine within an appliance, to name a few.

The steps of a method, process, or algorithm described in connection with the embodiments disclosed herein can be embodied directly in hardware, in a software module executed by a processor, or in a combination of the two. A software module can reside in RAM memory, flash memory, ROM memory, EPROM memory, EEPROM memory, registers, hard disk, a removable disk, a CD-ROM, or any other form of non-transitory computer-readable storage medium, media, or physical computer storage known in the art. An exemplary storage medium can be coupled to the processor such that the processor can read information from, and write information to, the storage medium. In the alternative, the storage medium can be integral to the processor. The processor and the storage medium can reside in an ASIC. The ASIC can reside in a user terminal. In the alternative, the processor and the storage medium can reside as discrete components in a user terminal.

Conditional language used herein, such as, among others, "can," "might," "may," "e.g.," and the like, unless specifically stated otherwise, or otherwise understood within the context as used, is generally intended to convey that certain embodiments include, while other embodiments do not include, certain features, elements and/or states. Thus, such conditional language is not generally intended to imply that features, elements and/or states are in any way required for one or more embodiments or that one or more embodiments necessarily include logic for deciding, with or without author input or prompting, whether these features, elements and/or states are included or are to be performed in any particular embodiment. The terms "comprising," "including," "having," and the like are synonymous and are used inclusively, in an open-ended fashion, and do not exclude additional elements, features, acts, operations, and so forth. Also, the term "or" is used in its inclusive sense (and not in its exclusive sense) so that when used, for example, to connect a list of elements, the term "or" means one, some, or all of the elements in the list.

While the above detailed description has shown, described, and pointed out novel features as applied to various embodiments, it will be understood that various omissions, substitutions, and changes in the form and details of the devices or algorithms illustrated can be made without departing from the spirit of the disclosure. As will be recognized, certain embodiments of the inventions described herein can be embodied within a form that does not provide all of the features and benefits set forth herein, as some features can be used or practiced separately from others.

What is claimed is:

1. A mobile pulse oximetry system for informing a user of mobile measurement of oxygen saturation ("SpO2"), the mobile pulse oximetry system comprising:

an SpO2 measurement system including:

an optical sensor configured to output one or more signals responsive to light from a light source attenuated by tissue of the user at a measurement site, said one or more signals responsive to an oxygen saturation of said tissue; and

a processing board in data communication with the optical sensor and a mobile computing device including a display and cellular communication, wherein the processing board is configured to:

receive said one or more signals from the optical sensor;

process said one or more signals to generate SpO2 measurement values; and

output the SpO2 measurement values to the mobile computing device; and

one or more hardware processors of the mobile computing device configured to execute an application, the application configured to execute commands to:

generate a graphical user interface having a plurality of display portions;

display, in at least one portion of the plurality of display portions, a representation of a physiological parameter of a plurality of physiological parameters comprising at least the SpO2 measurement values; and

display, in a different portion of the plurality of display portions, a plurality of user inputs configured to allow the user to interact with at least one of the plurality of display portions or the application;

wherein the processing of the one or more signals to generate SpO2 measurement values is performed only on the processing board, thereby freeing up memory available to the mobile computing device; and

wherein the processing board is configured to draw power for operation from the mobile computing device.

2. The mobile pulse oximetry system of claim **1**, wherein the application is configured to execute commands to:

perform a trend analysis on received SpO2 measurement values; and

display results of the trend analysis in at least one portion of the plurality of display portions.

3. The mobile pulse oximetry system of claim **2**, wherein the display is touch-sensitive, and wherein the application is configured to execute commands to narrow or expand the displayed results of the trend analysis in response to the user using a pinch gesture.

4. The mobile pulse oximetry system of claim **1**, wherein the application is configured to execute commands to set reminders to take future measurements.

5. The mobile pulse oximetry system of claim **1**, wherein the application is configured to execute commands to output one or more alarms associated with SpO2 measurement values that are above or below threshold SpO2 measurement values.

6. The mobile pulse oximetry system of claim **1**, wherein the application is configured to execute commands to output one or more reminders to use the optical sensor to take measurements of SpO2 measurement values at predetermined times or cycles.

7. The mobile pulse oximetry system of claim **1**, wherein the application is configured to execute commands to update the representation of the physiological parameter to comprise one or more of a plurality of graphical representations of the SpO2 measurement values, the plurality of graphical representations comprising at least one of bar graphs or charts.

8. The mobile pulse oximetry system of claim **1**, wherein the application is configured to execute commands to output an alert, via a network to a designated physician or other care provider, regarding abnormal SpO2 readings.

9. The mobile pulse oximetry system of claim **1**, wherein the mobile computing device comprises a smartphone.

10. The mobile pulse oximetry system of claim **1**, wherein the mobile computing device comprises a wearable computing device.

11. The mobile pulse oximetry system of claim **1**, wherein the mobile computing device comprises a wristwatch.

12. The mobile pulse oximetry system of claim **1**, wherein the SpO2 measurement system is configured to wirelessly transmit the SpO2 measurement values to the mobile computing device.

13. A computer-implemented method of informing a user of mobile measurement of oxygen saturation ("SpO2"), the computer-implemented method comprising:

outputting, from an optical sensor of an SpO2 measurement system, one or more signals responsive to light from a light source attenuated by tissue of the user at a measurement site, said one or more signals responsive to an oxygen saturation of said tissue; and

via a processing board of the SpO2 measurement system, the processing board in data communication with the optical sensor and a mobile computing device including a display:

receiving said one or more signals from the optical sensor;

processing said one or more signals to generate the SpO2 measurement values; and

outputting the SpO2 measurement values to the mobile computing device; and

via an application configured to execute commands on the mobile computing device:

generating a graphical user interface having a plurality of display portions;

displaying, in at least one portion of the plurality of display portions, a representation of a physiological parameter of a plurality of physiological parameters comprising at least the SpO2 measurement values; and

displaying, in a different portion of the plurality of portions, a plurality of user inputs configured to allow the user to interact with at least one of the plurality of display portions or the application.

14. The computer-implemented method of claim **13**, further comprising, via the application:

performing a trend analysis on received SpO2 measurement values; and

displaying results of the trend analysis in at least one portion of the plurality of display portions.

15. The computer-implemented method of claim **13**, further comprising, via the application, outputting one or more alarms associated with SpO2 measurement values that are above or below threshold SpO2 measurement values.

16. The computer-implemented method of claim **13**, further comprising, via the application, outputting one or more reminders to use the opticcal snesor to take measurements of SpO2 measurement values at predetermined times or cycles.

17. The computer-implemented method of claim **13**, further comprising, via the application, updating the representation of the physiological parameter to comprise one or more of a plurality of graphical representations of the SpO2 measurement values, the plurality of graphical representations comprising at least one of bar graphs or charts.

18. The computer-implemented method of claim **13**, further comprising, via the application, outputting an alert, via a network to a designated physician or other care provider, regarding abnormal SpO2 readings.

19. The computer-implemented methof od claim **13**, further comprising wirelessly transmitting the SpO**2** measurement values from the SpO**2** measurement system to the mobile computing device.

20. The computer-implemented method of claim **13**, further comprising, via the application, enabling the user to set reminders to take future measurements.

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Al-Ali et al.

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(54) **NONINVASIVE MULTI-PARAMETER PATIENT MONITOR**

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(52) **U.S. Cl.** **600/310**; 600/323; 600/324; 600/326

(58) **Field of Classification Search** 600/309–344
See application file for complete search history.

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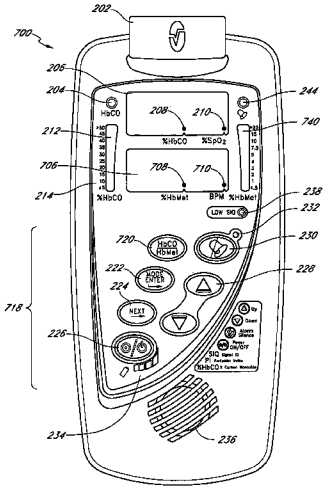
(57) **ABSTRACT**

Embodiments of the present disclosure include a handheld multi-parameter patient monitor capable of determining multiple physiological parameters from the output of a light sensitive detector capable of detecting light attenuated by body tissue. For example, in an embodiment, the monitor is capable of advantageously and accurately displaying one or more of pulse rate, plethysmograph data, perfusion quality, signal confidence, and values of blood constituents in body tissue, including for example, arterial carbon monoxide saturation ("HbCO"), methemoglobin saturation ("HbMet"), total hemoglobin ("Hbt"), arterial oxygen saturation ("SpO_2"), fractional arterial oxygen saturation ("$SpaO_2$"), or the like. In an embodiment, the monitor advantageously includes a plurality of display modes enabling more parameter data to be displayed than the available physical display real estate.

47 Claims, 18 Drawing Sheets



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D361,840	S		8/1995	Savage et al.
D362,063	S		9/1995	Savage et al.
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D363,120	S		10/1995	Savage et al.
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RE35,122	E		12/1995	Corenman et al.
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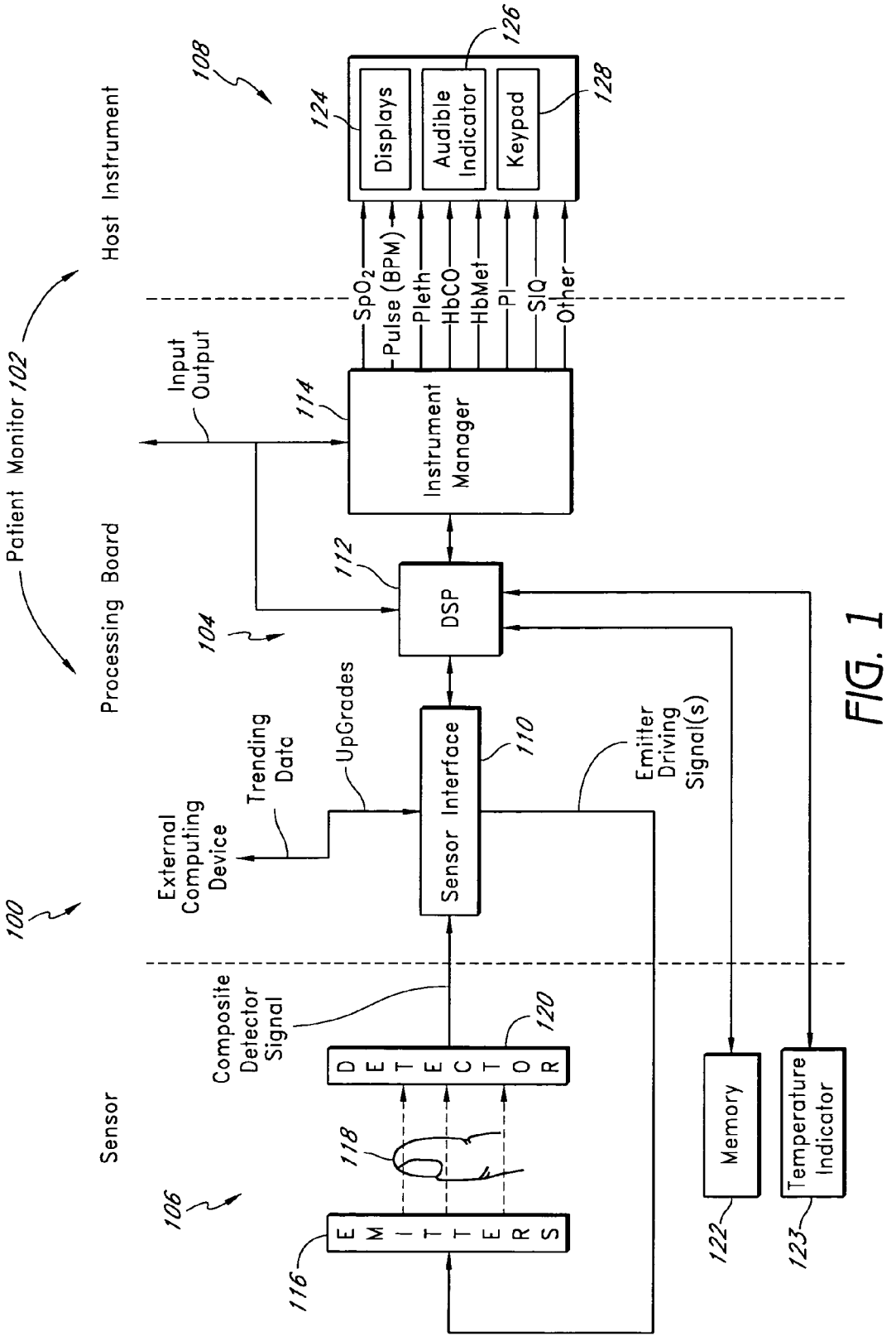
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Pleth
HbCO
HbMet
PI
SIQ
Other
Input
Output
114
Instrument Manager
112
DSP
104
Trending Data
UpGrades
110
Sensor Interface
Emitter Driving Signal(s)
External Computing Device
Composite Detector Signal
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DETECTOR
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EMITTERS
116
Memory
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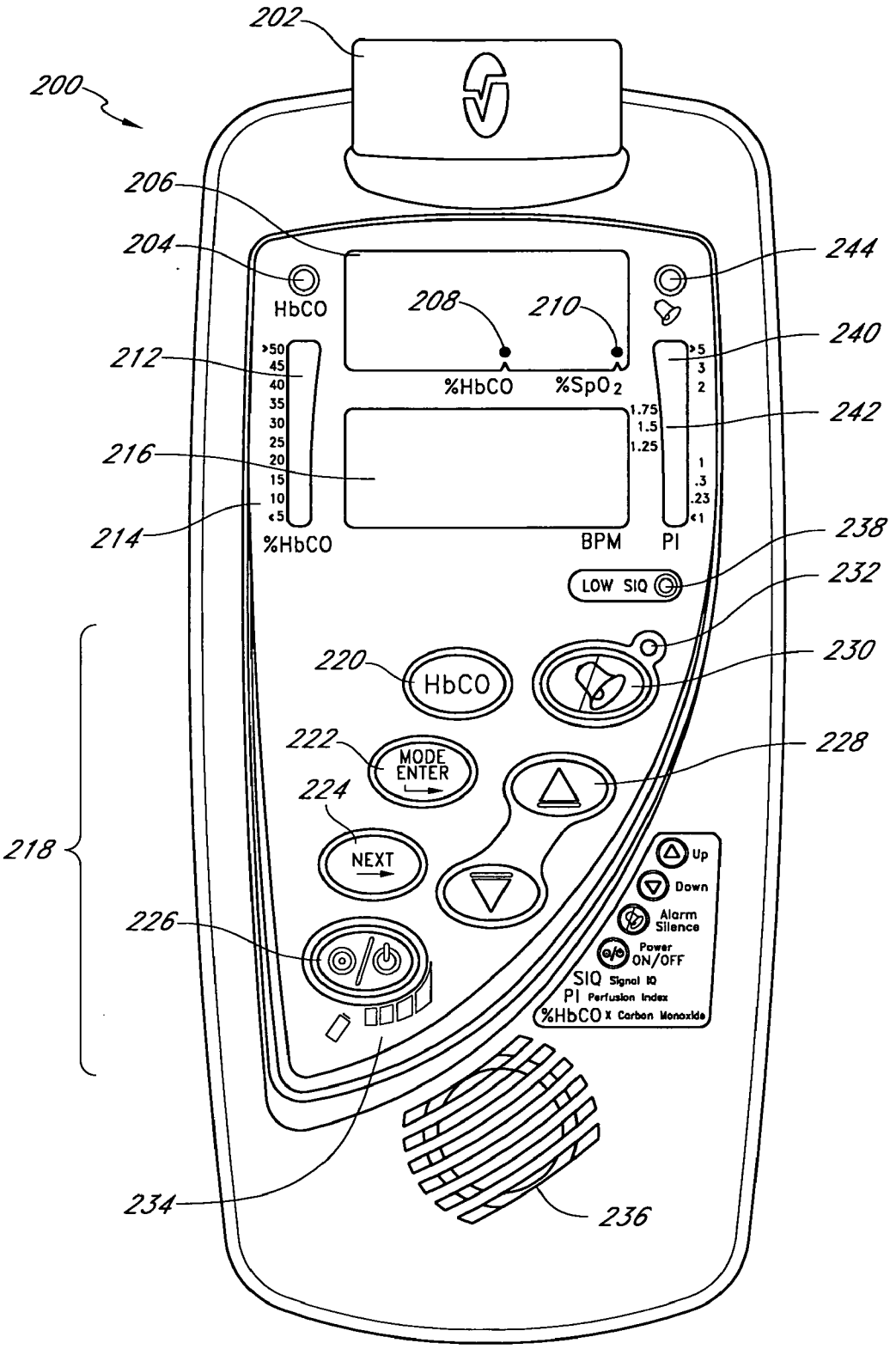
Temperature Indicator
123

FIG. 1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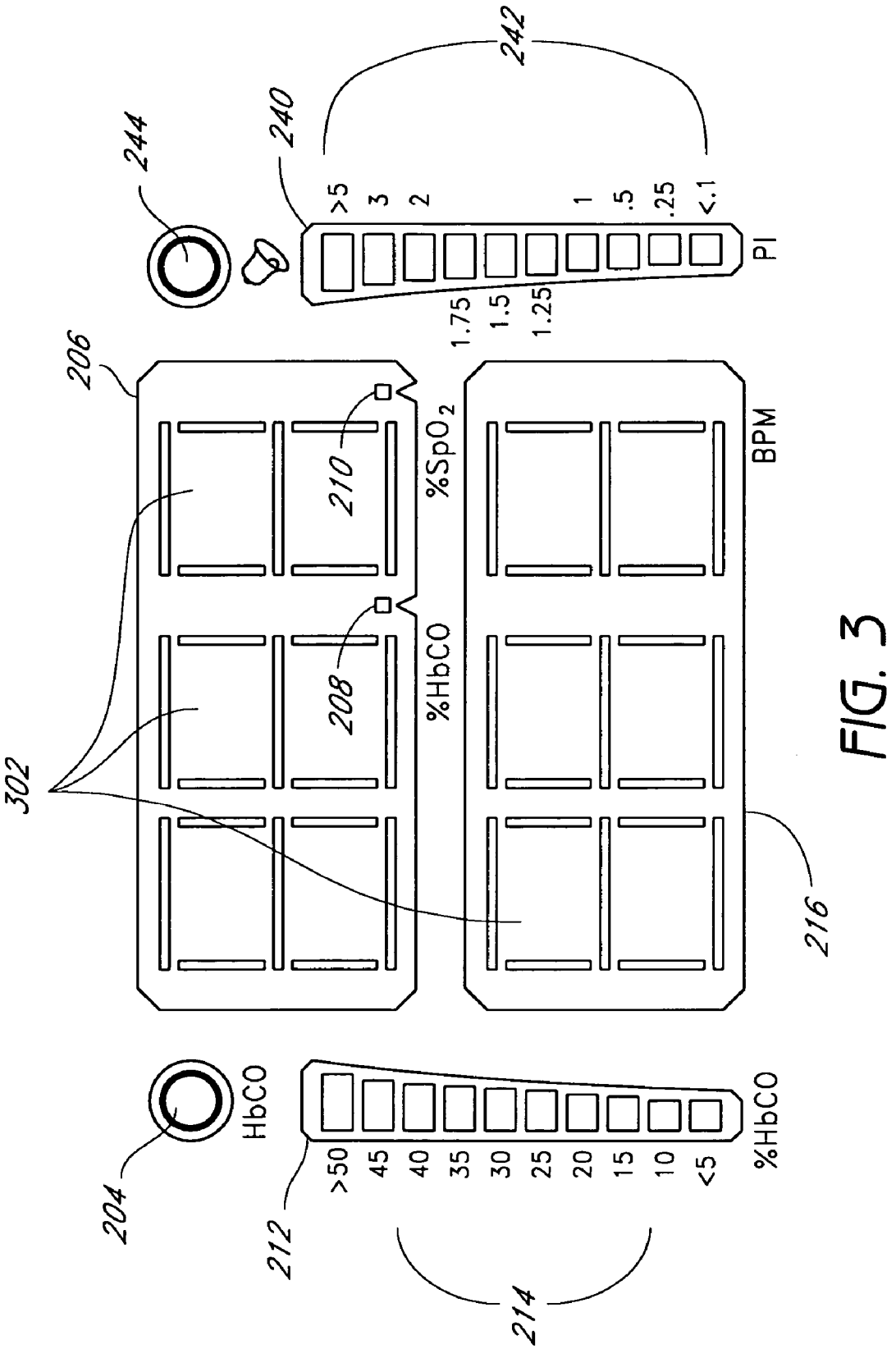
206
204
244
HbCO
208
210
240
212
%HbCO
%SpO2
242
216
214
%HbCO
BPM
PI
238
LOW SIQ
232
220
HbCO
230
222
MODE ENTER
228
224
218
NEXT
Up
Down
Alarm Silence
Power ON/OFF
SIQ Signal IQ
PI Perfusion Index
%HbCO Carbon Monoxide
226
234
236

FIG. 2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206
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%SpO2
BPM
208
%HbCO
302
216
HbCO
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>50
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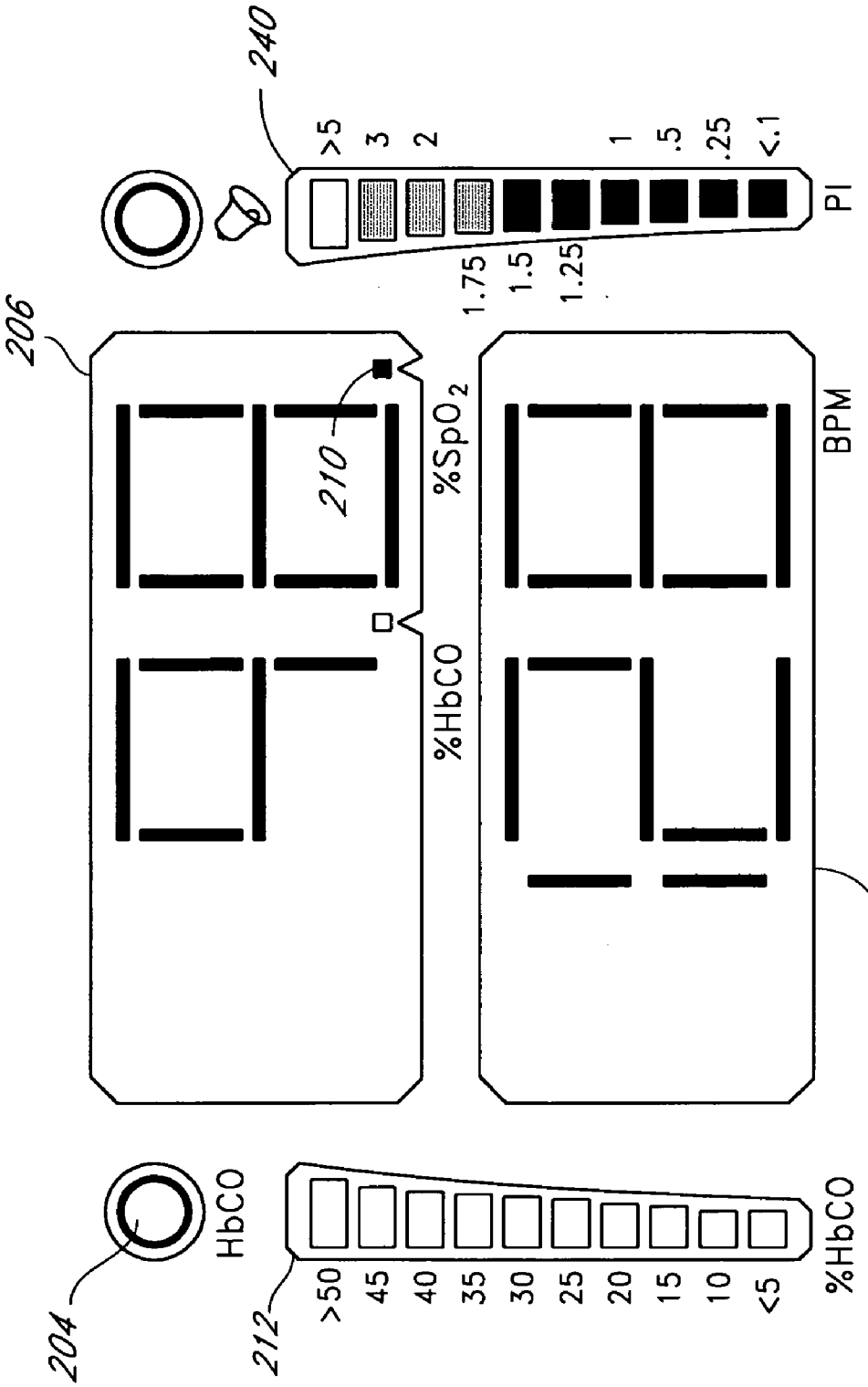
40
35
30
25
20
15
10
<5
%HbCO
212
214

FIG. 3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BPM
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25
20
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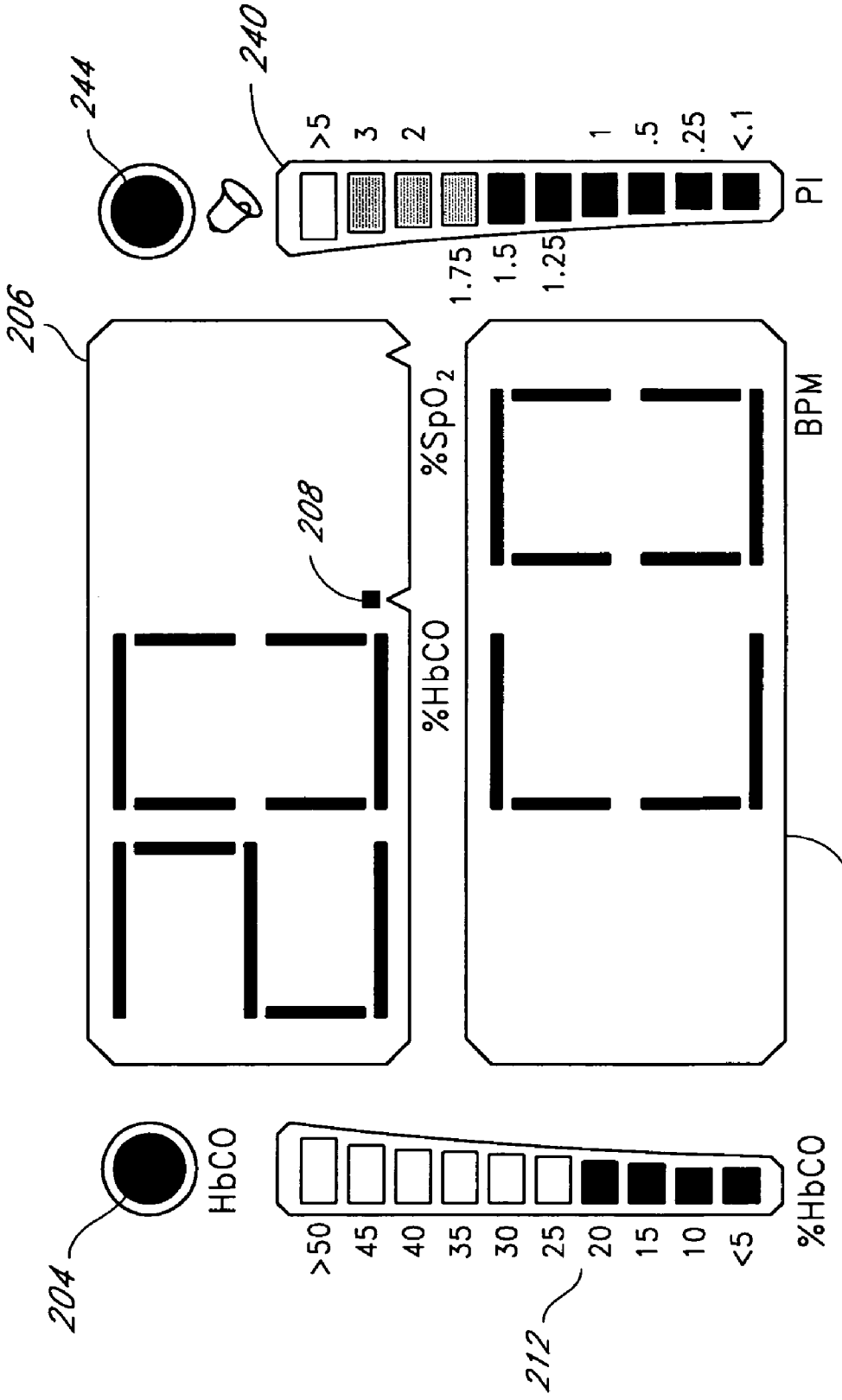
<5
%HbCO

FIG. 4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BPM
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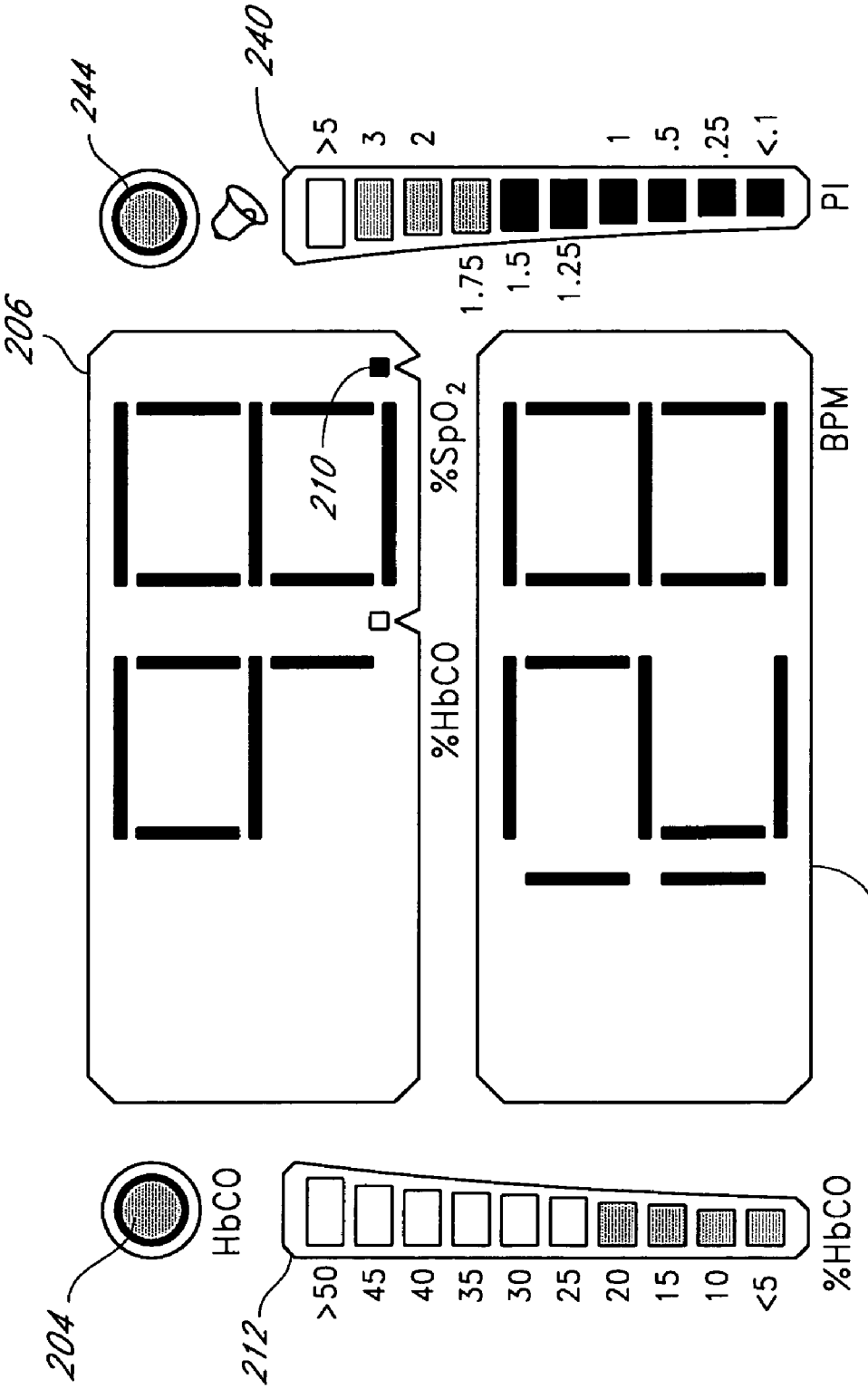
40
35
30
25
20
15
10
<5
%HbCO
212

FIG. 5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1.25
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210
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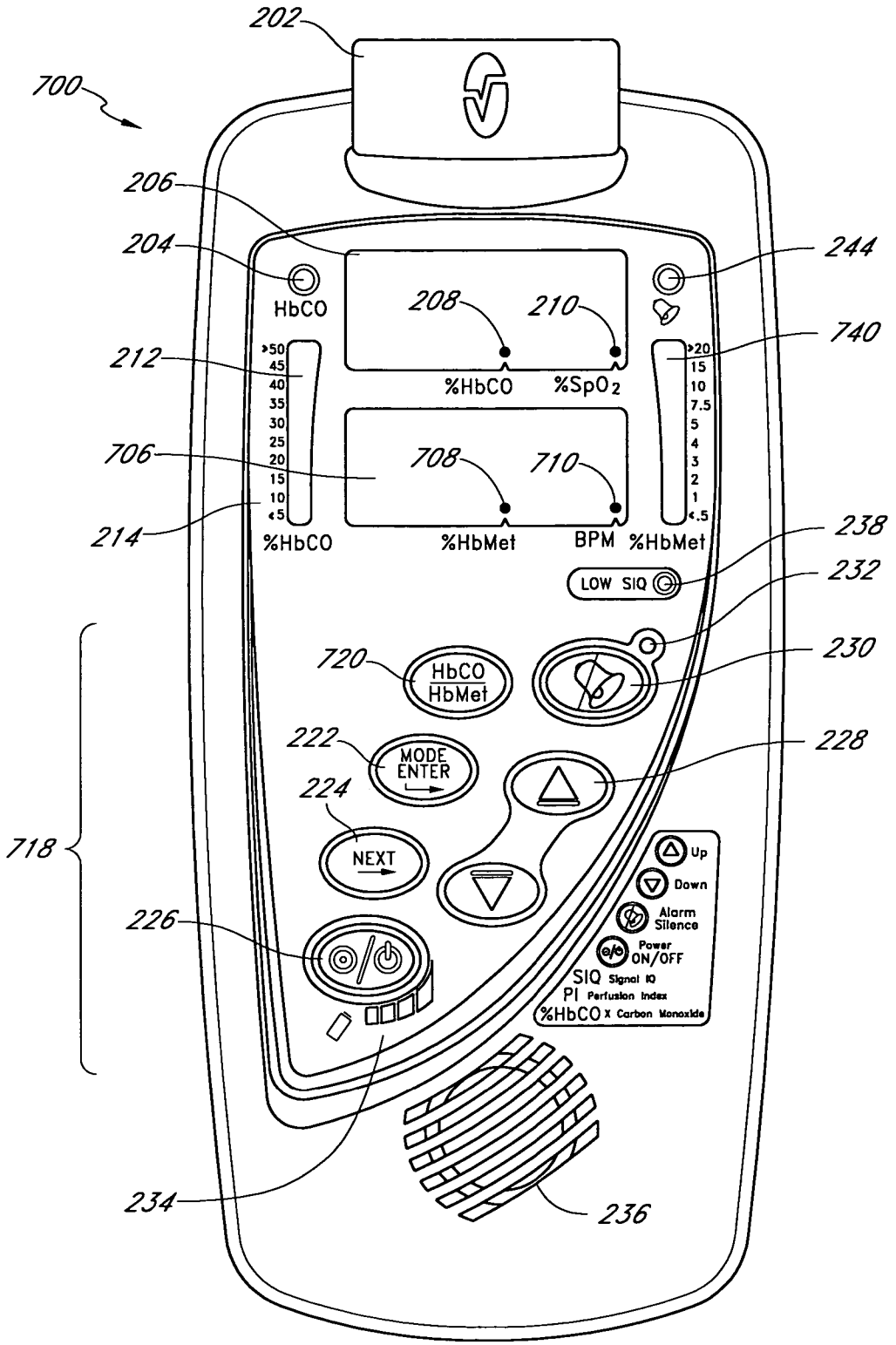
BPM
%HbCO
216
HbCO
204
212
>50
45
40
35
30
25
20
15
10
<5
%HbCO

FIG. 6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210
740
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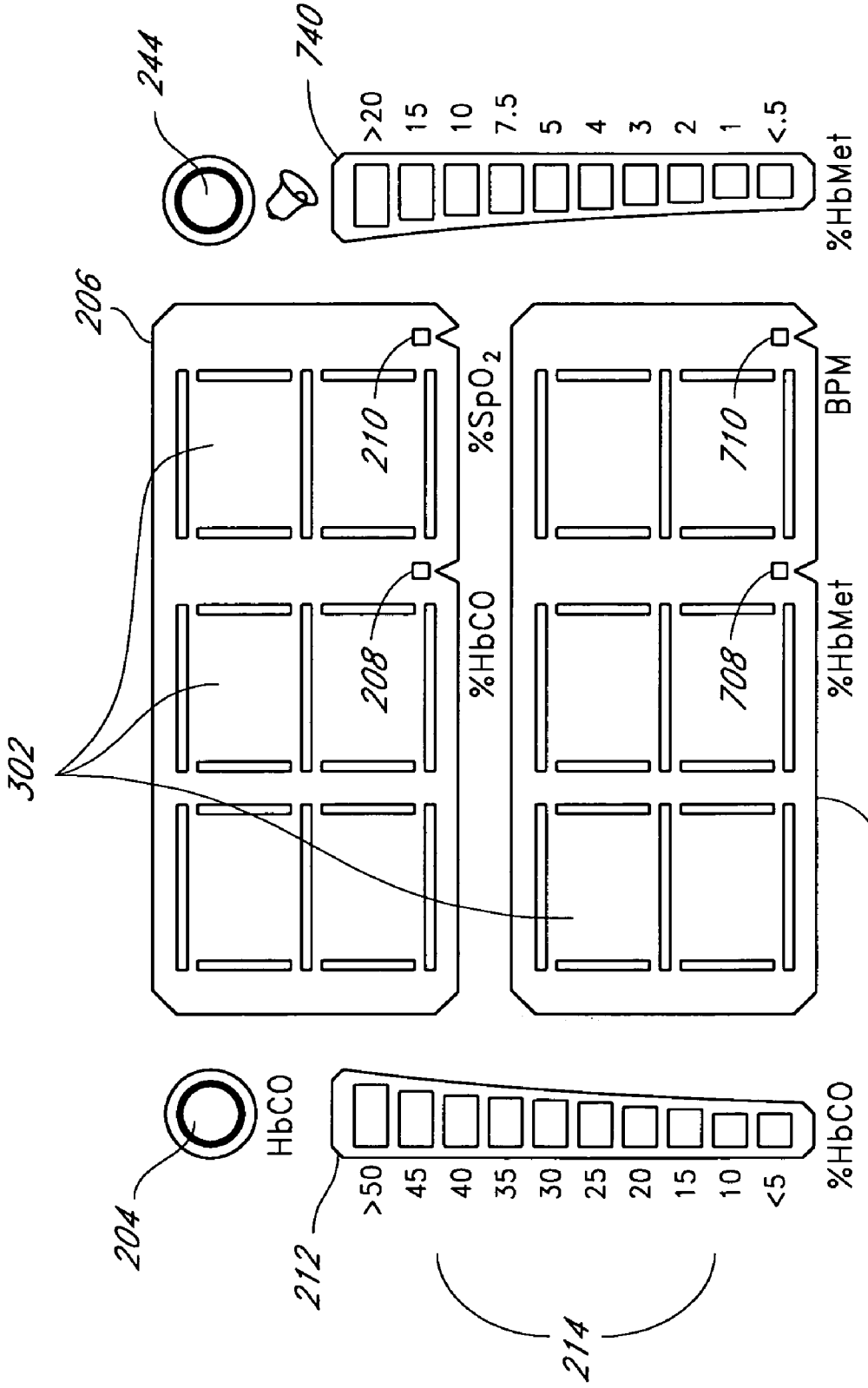
%SpO2
706
708
710
214
%HbCO
%HbMet
BPM
%HbMet
238
LOW SIQ
232
720
HbCO
HbMet
230
222
MODE
ENTER
228
224
NEXT
718
Up
Down
Alarm
Silence
Power
ON/OFF
SIQ Signal IQ
PI Perfusion Index
%HbCO Carbon Monoxide
226
234
236

FIG. 7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206
210
%SpO2
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BPM
208
%HbCO
708
%HbMet
302
706
204
HbCO
>50
45
40
35
30
25
20
15
10
<5
%HbCO
212
214

FIG. 8

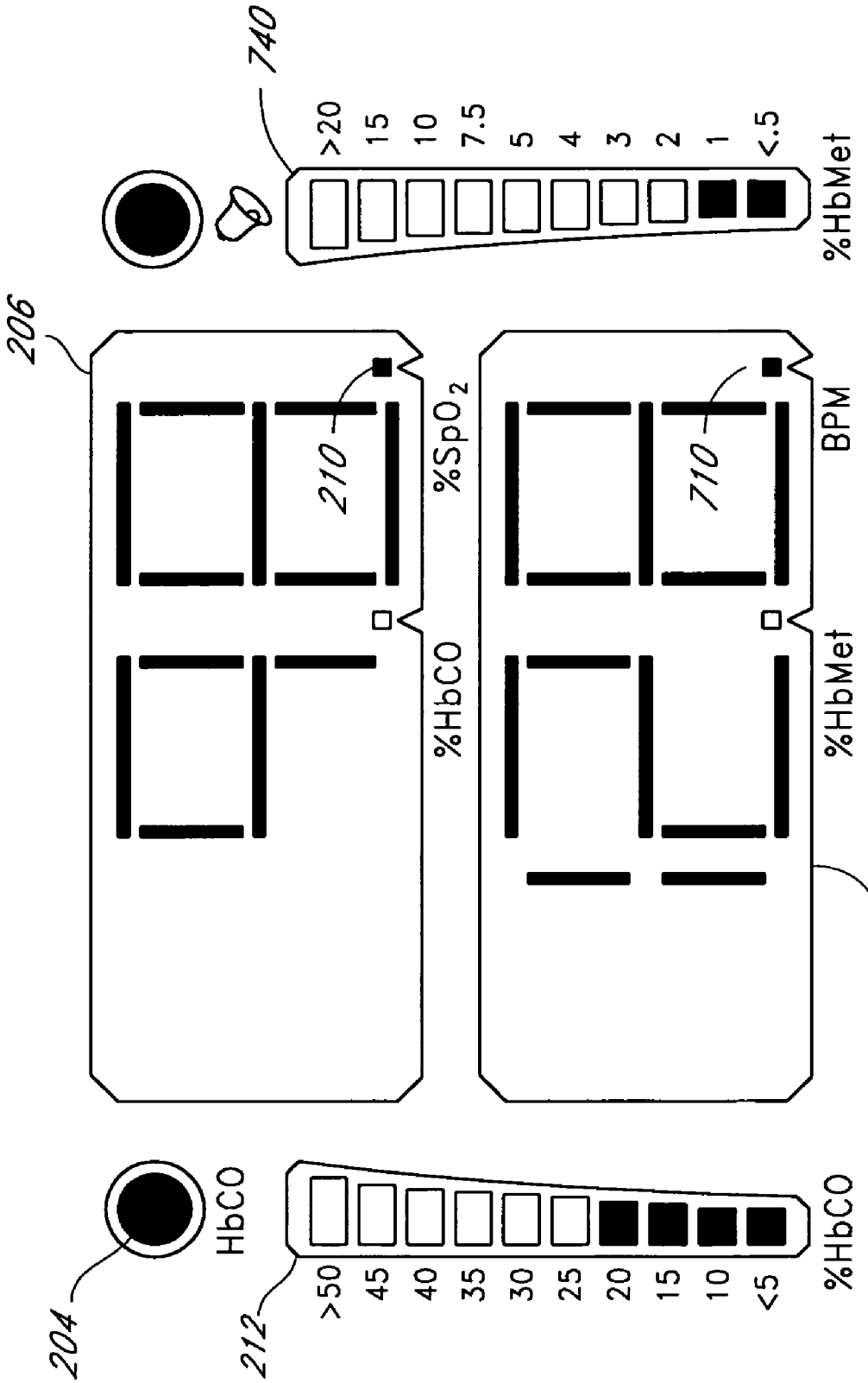

740
>20
15
10
7.5
5
4
3
2
1
<.5
%HbMet
206
210
%SpO2
%HbCO
710
BPM
%HbMet
706
204
HbCO
212
>50
45
40
35
30
25
20
15
10
<5
%HbCO

FIG. 9

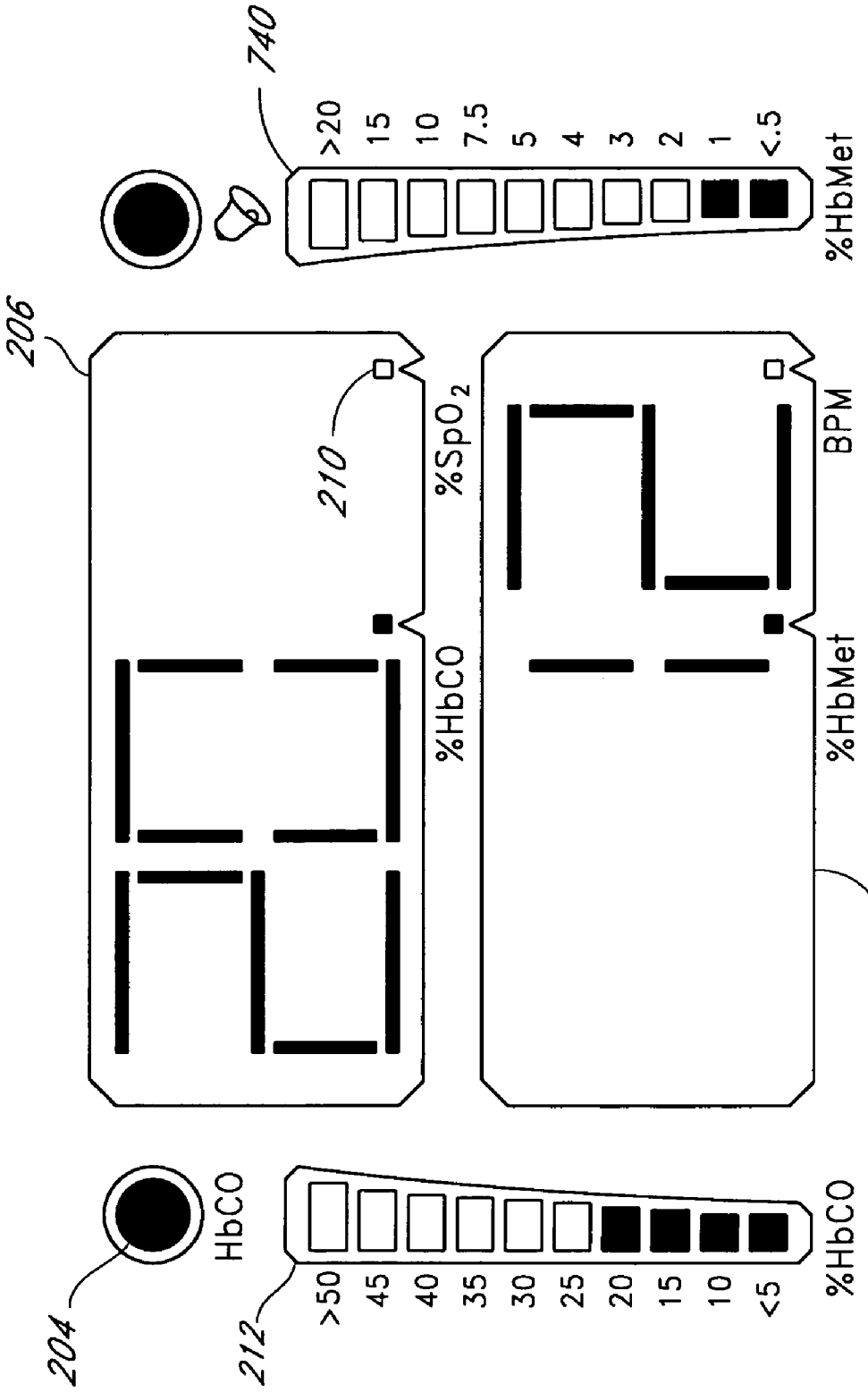

740
>20
15
10
7.5
5
4
3
2
1
<.5
%HbMet
206
210
%SpO2
%HbCO
BPM
%HbMet
706
204
HbCO
212
>50
45
40
35
30
25
20
15
10
<5
%HbCO

FIG. 10

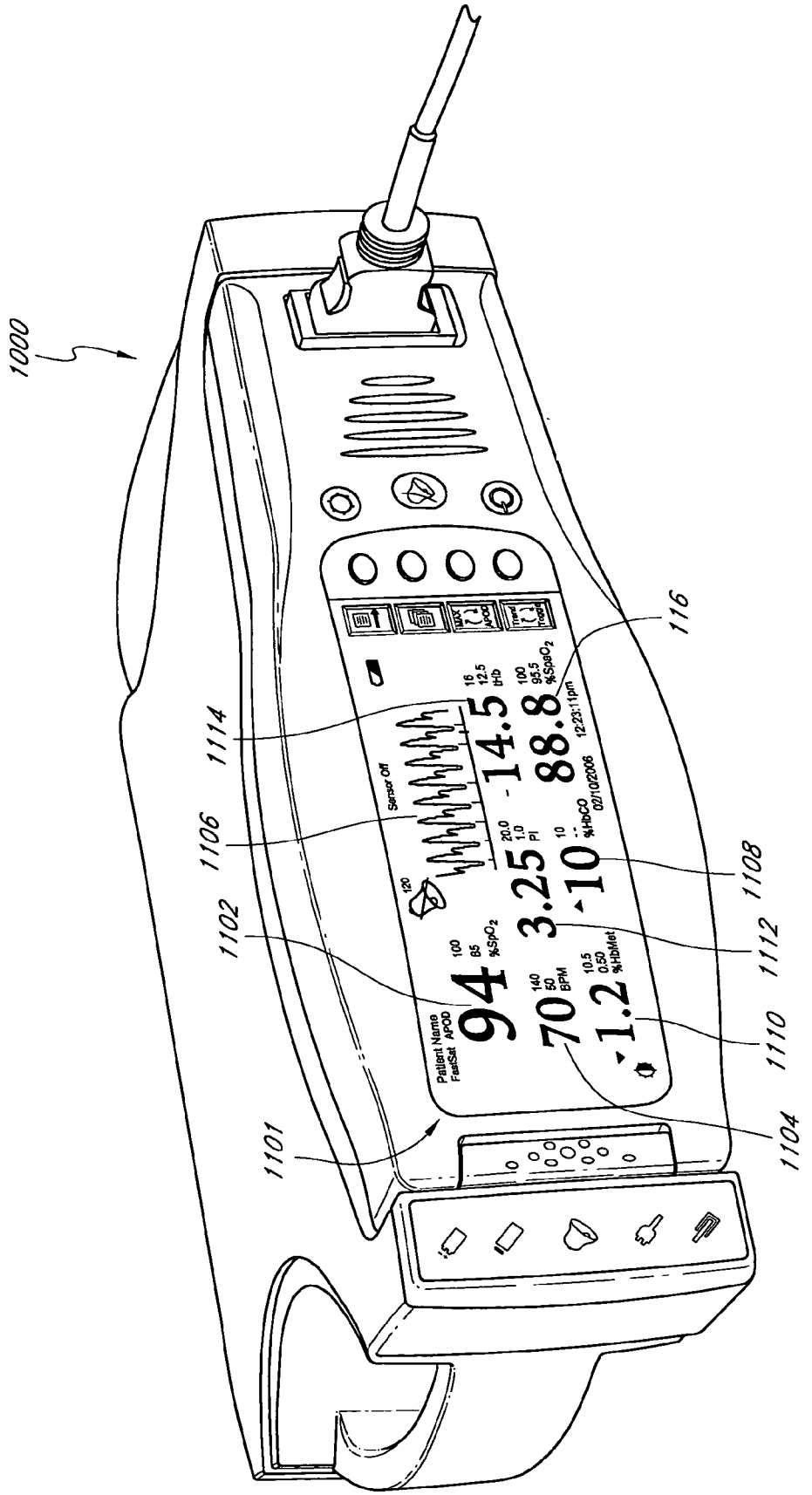

1000
1114
1106
1102
1101
116
1108
1112
1110
1104
Sensor Off
14.5
88.8
3.25
-10
94
70
-1.2
Patient Name
FastSat APOD

FIG. 11A

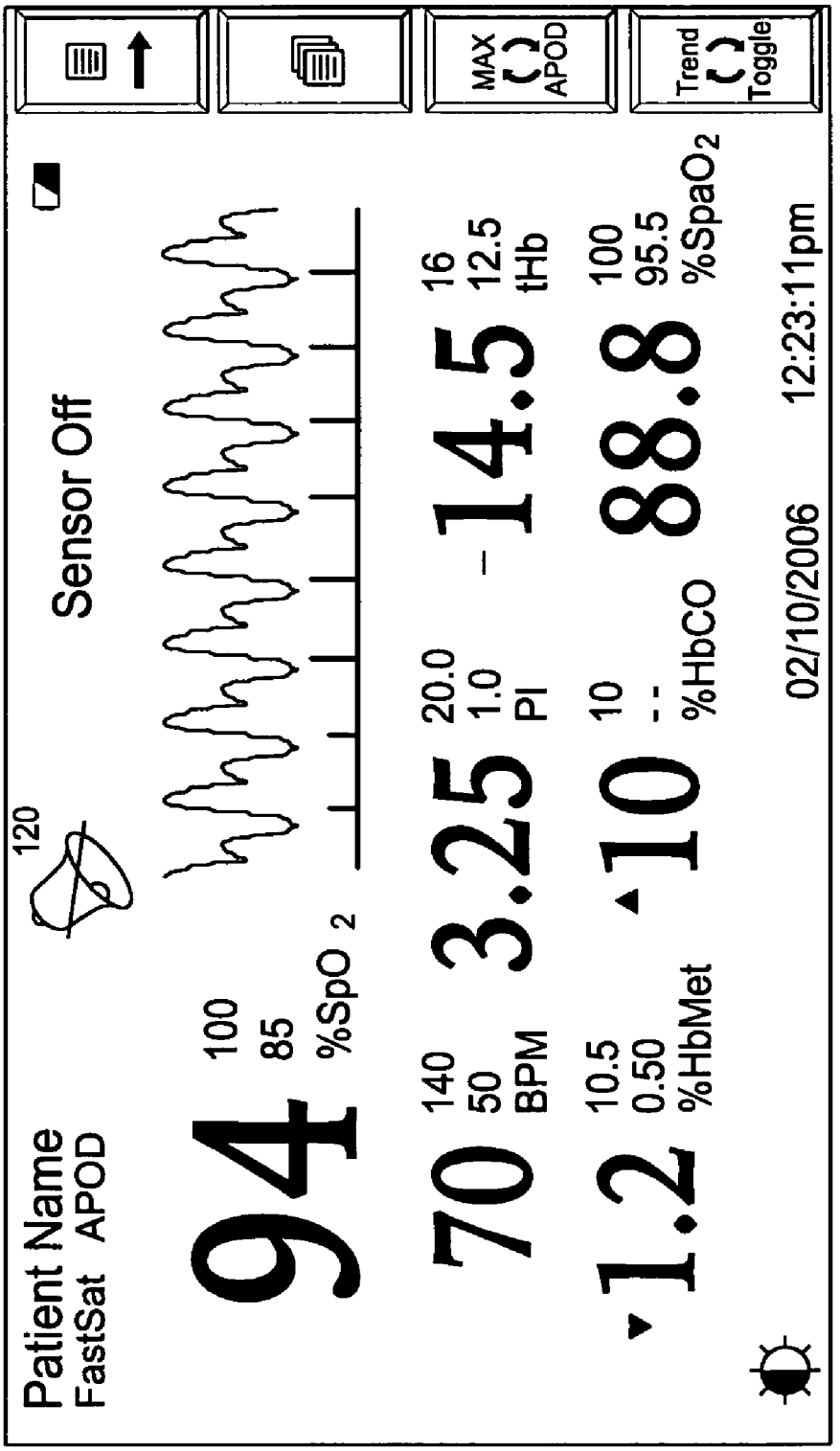

MAX APOD
Trend Toggle
Sensor Off
Patient Name
FastSat APOD
120
94
100
85
%SpO 2
70
140
50
BPM
1.2
10.5
0.50
%HbMet
3.25
20.0
1.0
PI
10
10
--
%HbCO
14.5
16
12.5
tHb
88.8
100
95.5
%SpaO2
02/10/2006
12:23:11pm

FIG. 11B

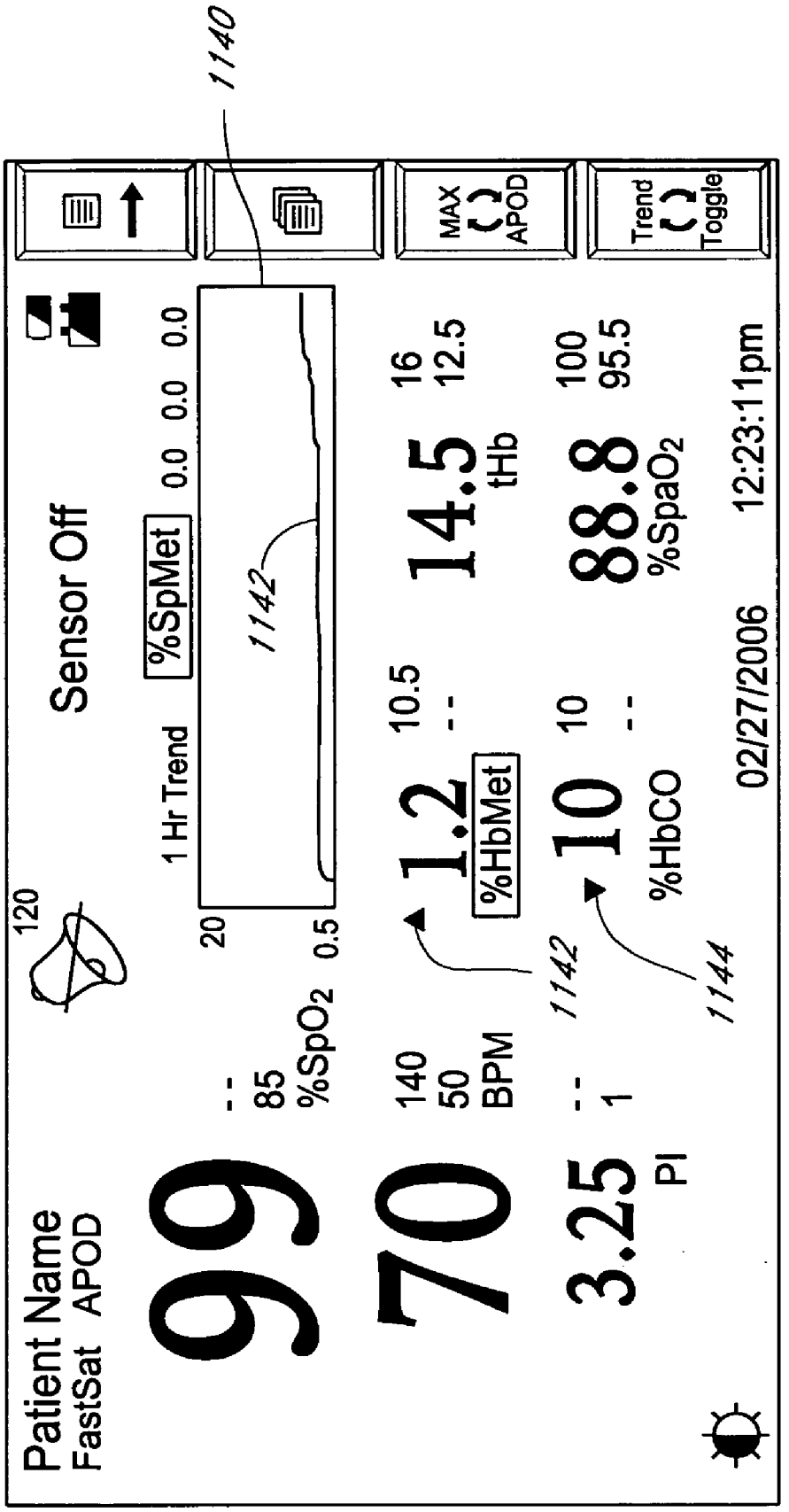

1140
MAX APOD
Trend Toggle
Sensor Off
120
1 Hr Trend
%SpMet
0.0
0.0
0.0
0.0
1142
20
0.5
%SpO2
85
--
99
140
50
BPM
70
1.2
10.5
--
%HbMet
1142
10
10
--
%HbCO
1144
3.25
--
1
PI
14.5
16
12.5
tHb
88.8
100
95.5
%SpaO2
02/27/2006
12:23:11pm
Patient Name
FastSat APOD

FIG. 11C

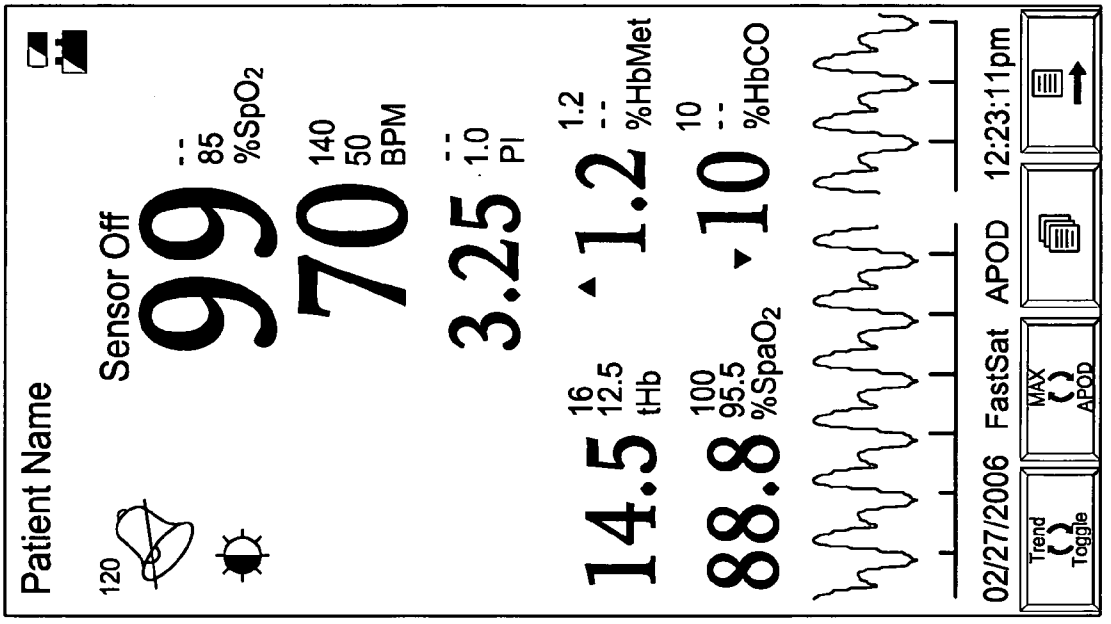

Patient Name
Sensor Off
99
85
%SpO2
70
140
50
BPM
3.25
1.0
PI
14.5
16
12.5
tHb
1.2
1.2
%HbMet
88.8
100
95.5
%SpaO2
10
10
%HbCO
02/27/2006
FastSat
APOD
12:23:11pm
Trend
Toggle
MAX
APOD

FIG. 11D

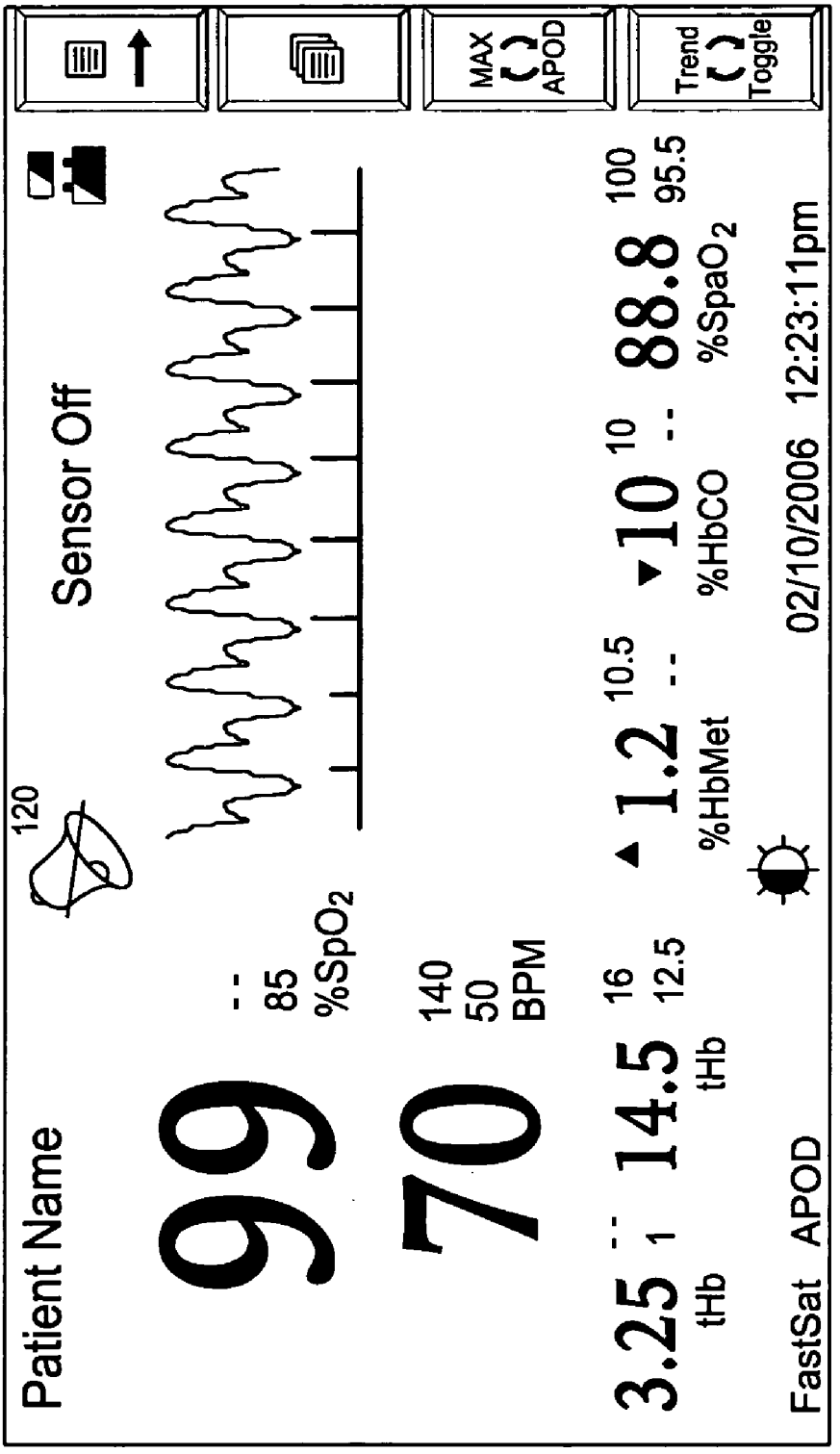

MAX APOD
Trend Toggle
Sensor Off
Patient Name
120
99
-- 85
%SpO2
70
140 50
BPM
3.25 -- 1 tHb
14.5 16 12.5
tHb
1.2 10.5 --
%HbMet
10 10 --
%HbCO
88.8 100 95.5
%SpaO2
02/10/2006 12:23:11pm
FastSat APOD

FIG. 11E

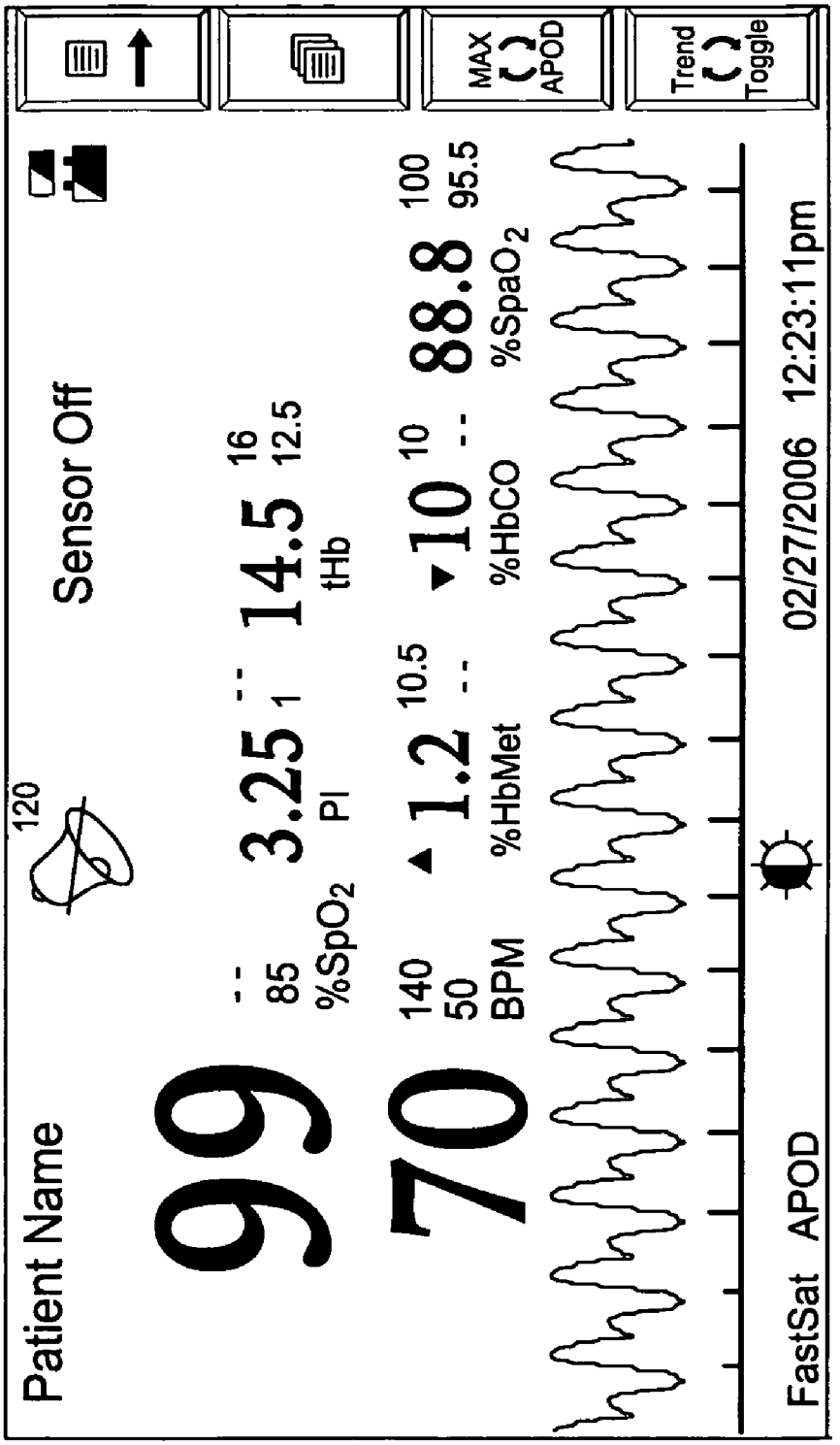

MAX APOD
Trend Toggle
Sensor Off
Patient Name
120
99
%SpO2
85
--
70
BPM
140
50
3.25
PI
1
--
1.2
%HbMet
10.5
--
14.5
tHb
16
12.5
10
%HbCO
10
--
88.8
%SpaO2
100
95.5
02/27/2006 12:23:11pm
FastSat APOD

FIG. 11F

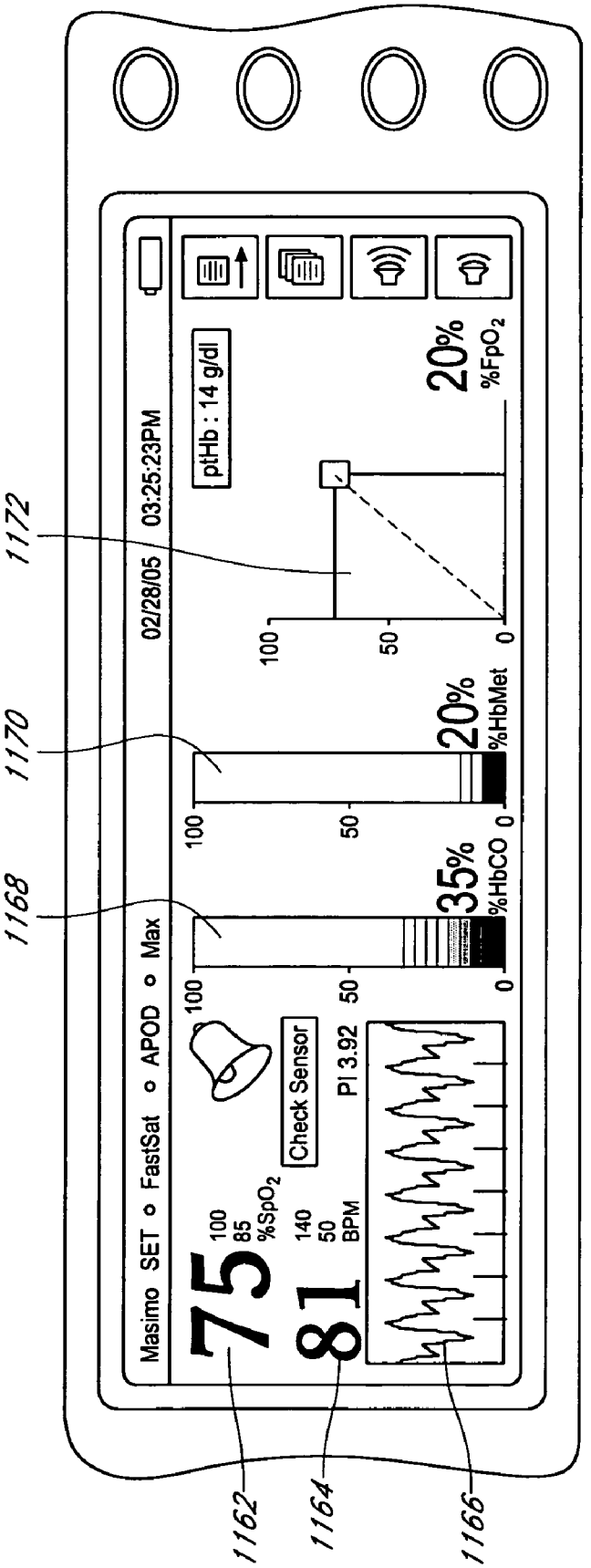

1172
1170
1168
1162
1164
1166
Masimo SET ○ FastSat ○ APOD ○ Max
02/28/05 03:25:23PM
ptHb : 14 g/dl
20% %FpO2
20% %HbMet
35% %HbCO
100
50
0
Check Sensor
PI 3.92
75
81
100
85
%SpO2
140
50
BPM

FIG. 11G

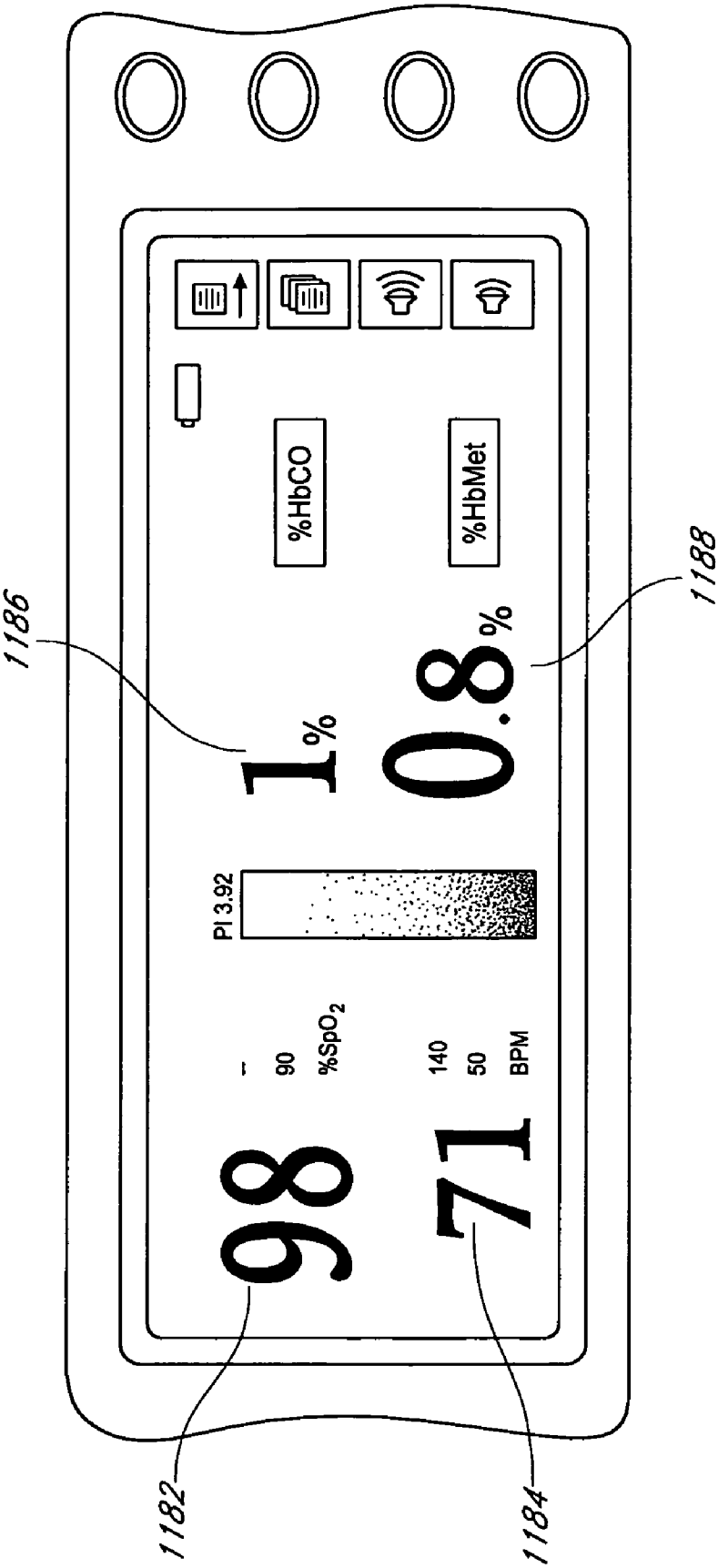

%HbCO
%HbMet
1186
1188
1%
0.8%
PI 3.92
%SpO2
90
140
50
BPM
98
71
1182
1184

FIG. 11H

NONINVASIVE MULTI-PARAMETER PATIENT MONITOR

PRIORITY CLAIM TO RELATED PROVISIONAL APPLICATIONS

The present application claims priority benefit under 35 U.S.C. §119(e) to U.S. Provisional Patent Application Ser. No. 60/657,596, filed Mar. 1, 2005, entitled "Multiple Wavelength Sensor," No. 60/657,281, filed Mar. 1, 2005, entitled "Physiological Parameter Confidence Measure," No. 60/657,268, filed Mar. 1, 2005, entitled "Configurable Physiological Measurement System," and No. 60/657,759, filed Mar. 1, 2005, entitled "Noninvasive Multi-Parameter Patient Monitor." The present application incorporates the foregoing disclosures herein by reference.

INCORPORATION BY REFERENCE OF RELATED UTILITY APPLICATIONS

The present application is related to the following copending U.S. utility applications:

	App. Sr. No.	Filing Date	Title	Atty Dock.
1	11/367,013	Mar. 1, 2006	Multiple Wavelength Sensor Emitters	MLR.002A
2	11/366,995	Mar. 1, 2006	Multiple Wavelength Sensor Equalization	MLR.003A
3	11/366,209	Mar. 1, 2006	Multiple Wavelength Sensor Substrate	MLR.004A
4	11/366,210	Mar. 1, 2006	Multiple Wavelength Sensor Interconnect	MLR.005A
5	11/366,833	Mar. 1, 2006	Multiple Wavelength Sensor Attachment	MLR.006A
6	11/366,997	Mar. 1, 2006	Multiple Wavelength Sensor Drivers	MLR.009A
7	11/367,034	Mar. 1, 2006	Physiological Parameter Confidence Measure	MLR.010A
8	11/367,036	Mar. 1, 2006	Configurable Physiological Measurement System	MLR.011A
9	11/367,014	Mar. 1, 2006	Noninvasive Multi-Parameter Patient Monitor	MLR.013A
10	11/366,208	Mar. 1, 2006	Noninvasive Multi-Parameter Patient Monitor	MLR.014A

The present application incorporates the foregoing disclosures herein by reference.

FIELD OF THE DISCLOSURE

The present disclosure relates to the field of noninvasive patient monitors. More specifically, the disclosure relates to monitors displaying measurements derived using signals from optical sensors.

BACKGROUND

Spectroscopy is a common technique for measuring the concentration of organic and some inorganic constituents of a solution. The theoretical basis of this technique is the Beer-Lambert law, which states that the concentration c_i of an absorbent in solution can be determined by the intensity of light transmitted through the solution, knowing the path-length d_λ, the intensity of the incident light $I_{0,\lambda}$, and the extinction coefficient $\epsilon_{i,\lambda}$ at a particular wavelength λ. In generalized form, the Beer-Lambert law is expressed as:

$$I_\lambda = I_{0,\lambda} e^{-d_\lambda \cdot \mu_{0,\lambda}} \quad (1)$$

$$\mu_{0,\lambda} = \sum_{i=1}^{n} \varepsilon_{i,\lambda} \cdot c_i \quad (2)$$

where $\mu_{0,\lambda}$ is the bulk absorption coefficient and represents the probability of absorption per unit length. The minimum number of discrete wavelengths that are required to solve Equations 1-2 are the number of significant absorbers that are present in the solution.

A practical application of this technique is pulse oximetry, which utilizes a noninvasive sensor to measure oxygen saturation (SpO_2) and pulse rate. In general, the sensor has light emitting diodes (LEDs) that transmit optical radiation of red and infrared wavelengths into a tissue site and a detector that responds to the intensity of the optical radiation after absorption (e.g., by transmission or transreflectance) by pulsatile arterial blood flowing within the tissue site. Based on this response, a processor determines measurements for SpO_2, pulse rate, and can output representative plethysmographic waveforms. Thus, "pulse oximetry" as used herein encompasses its broad ordinary meaning known to one of skill in the art, which includes at least those noninvasive procedures for measuring parameters of circulating blood through spectroscopy. Moreover, "plethysmograph" as used herein (commonly referred to as "photoplethysmograph"), encompasses its broad ordinary meaning known to one of skill in the art, which includes at least data representative of a change in the absorption of particular wavelengths of light as a function of the changes in body tissue resulting from pulsing blood.

Pulse oximeters capable of reading through motion induced noise are available from Masimo Corporation ("Masimo") of Irvine, Calif. Moreover, portable and other oximeters capable of reading through motion induced noise are disclosed in at least U.S. Pat. Nos. 6,770,028, 6,658,276, 6,157,850, 6,002,952, and 5,769,785. Read which are owned by Masimo, and are incorporated by reference herein. Such reading through motion oximeters have gained rapid acceptance in a wide variety of medical applications, including surgical wards, intensive care and neonatal units, general wards, home care, physical training, and virtually all types of monitoring scenarios.

SUMMARY OF THE DISCLOSURE

Despite the success of read through motion oximeter systems, there is a need to provide patient monitors capable of displaying multiple physiological parameters, other than or in addition to SpO_2, plethysmograph waveforms, or pulse rates. For example, in accessing a patient's condition, caregivers often desire knowledge of other blood constituents, including for example, a percent value for arterial carbon monoxide saturation ("HbCO") or a percent value for methemogobin saturation ("HbMet") or the like. For example, in an embodiment, the display advantageously displays one or more of the following: pulse rate, plethysmograph waveform data, perfusion index, values of blood constituents in body tissue, including for example, HbCO, HbMet, total hemoglobin ("Hbt"), arterial oxygen saturation ("SpO_2"), fractional arterial oxygen saturation ("$SpaO_2$"), or the like. In other embodiments, the monitor may advantageously and accurately determine values for one or more of HbO_2, Hb, blood glucose,

water, the presence or absence of therapeutic drugs (aspirin, Dapson, nitrates, or the like) or abusive/recreational drugs (methamphetamine, alcohol, steroids, or the like), concentrations of carbon dioxide ("CO_2") or oxygen ("O"), ph levels, bilirubin, perfusion quality, signal quality or the like. Accordingly, the present disclosure includes a multi-parameter patient monitor capable of determining one or more of the foregoing parameters, other than or in addition to, SpO_2, plethysmograph waveforms, or perfusion quality index.

In an embodiment, the display of a noninvasive multi-parameter patient monitor advantageously includes a plurality of display modes enabling more parameter data to be displayed than the available physical display area or real estate. In an embodiment, a user may cycle different parameter values through an area of the display common to both parameters even when one parameter is shifted, through, for example, actuation of a user input key. The patient monitor may also display different parameters as color-coded. For example, when the following measured parameters are within "normal" ranges, SpO_2 may be displayed red, pulse rate (BPM) may be displayed green, HbCO may be displayed orange, HbMet may be displayed blue, or the like. In an embodiment, measured values of SpO_2 may be displayed in white, BPM may be displayed in yellow green or aquamarine, PI™ may be displayed in violet, Hbt may be displayed in grass green, HbMet may be displayed in blue or light blue, HbCO may be displayed in orange, and $SpaO_2$ may be displayed in electric blue.

Moreover, parameter trend data may also be displayed using the same or similar color coding, especially when multiple trends are displayed on one or more display graphs. In addition, more coarse or gross parameter indications may be displayed for quick reference to indicate to a caregiver whether any of a variety of monitored parameters, such as, for example, SpO_2, HbCO or HbMet is within acceptable ranges. The monitor may advantageously include additional display information, such as, for example, parametric displays where one parameter is displayed as a function of another, three dimensional displays (for example, extending a parametric display along time or an additional parameter), directional indicators predicting where a parameter is likely heading or reporting a general direction a parameters has been trending, or the like.

In addition to the foregoing, caregivers often desire to more closely monitor parameters that are close to, approaching, or beyond normal safe thresholds. In an embodiment, the patient monitor provides an indication that the caregiver should change display modes to view more critical monitored parameters. In alternative embodiments, the patient monitor automatically changes display modes to show parameters moving closer to or beyond normal thresholds.

In an embodiment, the patient monitor includes an audible or visual indication of a type of sensor communicating with the monitor. For example, the monitor may determine how many wavelengths a particular attached sensor will emit through communication with memory devices associated with the attached sensor or cable.

Additional embodiments include audio or visual alarms for each of multiple monitored parameters, combinations of parameters, an indication of perfusion in the tissue of the measurement site, an indication of the confidence the signal processing has in its output measurements, or the like.

For purposes of summarization, certain aspects, advantages and novel features are described herein. Of course, it is to be understood that not necessarily all such aspects, advantages or features need to be present in any particular embodiment.

BRIEF DESCRIPTION OF THE DRAWINGS

The drawings and the associated descriptions are provided to illustrate embodiments of the disclosure and not to limit the scope of the claims.

FIG. **1** illustrates a block diagram of an exemplary embodiment of a patient monitoring system including a sensor and a multi-parameter patient monitor.

FIG. **2** illustrates a top elevation view of an exemplary handheld noninvasive multi-parameter patient monitor capable of displaying at least HbCO, such as, for example, the patient monitor of FIG. **1**.

FIG. **3** illustrates an exemplary display of the patient monitor of FIG. **2**.

FIG. **4** illustrates the display of FIG. **3** showing measured values of SpO_2, BPM, perfusion, and type of sensor according to an exemplary embodiment of the patient monitor of FIG. **1**.

FIG. **5** illustrates the display of FIG. **3** showing measured values of HbCO, perfusion, and type of sensor according to an exemplary embodiment of the patient monitor of FIG. **1**.

FIG. **6** illustrates the display of FIG. **3** showing measured values of SpO_2, HbCO, BPM, perfusion, and type of sensor, according to an exemplary embodiment of the patient monitor of FIG. **1**.

FIG. **7** illustrates a top elevation view of an exemplary handheld noninvasive multi-parameter patient monitor capable of displaying at least HbCO and HbMet, such as, for example, the patient monitor of FIG. **1**.

FIG. **8** illustrates an exemplary display of the patient monitor of FIG. **7**.

FIG. **9** illustrates the display of FIG. **8** showing measured values of SpO_2, BPM, HbCO, HbMet, and type of sensor according to an exemplary embodiment of the patient monitor of FIG. **1**.

FIG. **10** illustrates the display of FIG. **8** showing measured values of HbCO, HbMet, and type of sensor according to an exemplary embodiment of the patient monitor of FIG. **1**.

FIG. **11**A illustrates a perspective view of an exemplary noninvasive multi-parameter patient monitor such as, for example, the patient monitor of FIG. **1**.

FIGS. **11**B-**11**H illustrate display screens of the patient monitor of FIG. **11**A.

DETAILED DESCRIPTION OF PREFERRED AND ALTERNATIVE EMBODIMENTS

Embodiments of the present disclosure include a portable or other multi-parameter patient monitor capable of determining multiple physiological parameters from one or more signals output from one or more light sensitive detectors capable of detecting light attenuated by body tissue carrying pulsing blood. For example, in an embodiment, the monitor advantageously and accurately determines a wide variety of physiological parameters or other calculations as discussed above.

In an embodiment, the display of patient monitor advantageously includes a plurality of display modes enabling more parameter data to be displayed than the available physical display real estate. For example, the patient monitor may include one or more user input keys capable of toggling through measurement data. In an embodiment, the displays include mode indicators providing caregivers easily identifiable visual queues, such as LED's, text, icons, or other indicia providing readily identifiable queues as to which parameter is being displayed. In an embodiment, the display may shift, may be parameter color-coded, or the like to further ensure

quick comprehension of which measured parameter is the displayed parameter. For example, in an embodiment, the monitor displays SpO_2 in white, pulse rate (BPM) in green, HbCO in orange, and HbMet in blue when the respective measured parameter is within a "normal" range.

In an embodiment, the patient monitor provides an indication that the caregiver should change display modes to view more critical or time sensitive measured parameters, specific caregiver selected parameters, or the like. For example, the patient monitor may advantageously sound audio or visual alarms that alert the caregiver to particular one or more of worsening parameters, parameters changing in a predetermined pattern or rate, parameters stabilizing below user defined or safe thresholds, caregiver selected parameters, or the like. The monitor may also use alerts that provide audio or visual indications of the severity of the condition, severity of the change, or the like. In alternative embodiments, the patient monitor may automatically change display modes when a particular parameter crosses one or more thresholds. For example, a patient monitor may be displaying a first parameter, such as a plethysmograph, and upon determining measurements indicating that HBMet is trending toward an alarm condition, the monitor may automatically switch from displaying the first parameter to the alarming parameter, or in this case, a trend of the alarming parameter.

In an embodiment, a switch is provided to allow a user to switch displays to view an alarming measurement. In an embodiment, during an alarm condition, a parameter display may switch to a trend graph in the same or different color, line weight, flash, flash rate, intensity, size, or the like.

The patient monitor may also include one or more displays capable of displaying trend data for any one or more of the monitored or derived patient parameters. For example, the trend data may be displayed in graph form, may include multiple trend lines, each representing a different monitored or derived patient parameter. Moreover, each trend line may be color-coded to facilitate quick comprehension of which trend line represents which measured parameter. However, an artisan will recognize from the disclosure herein a large number of identification techniques including color-coding, identifying text, or the like. Additionally, user input may toggle displayed trend data, may select which parameters to display simultaneously, or the like.

In an embodiment, the patient monitor includes an audible or visual indication of a type of sensor communicating with the monitor. For example, the patient monitor may provide a particular audio or visual indication, such as a beep, LED activation, graphic activation, text messages, voice messages, or the like, to indicate communication with or connection to an approved sensor, patient cable, combination, or the like. In an embodiment, the indication may change based on the manufacturer, type of sensor recognized or not recognized, type of patient, type of physiological parameters measurable with the attached sensor, or the like. Additional embodiments include an indication of perfusion in the tissue of the measurement site and an indication of the confidence the signal processing has in its output measurements or input signal quality.

To facilitate an understanding of the disclosure, the remainder of the description references exemplary embodiments illustrated in the drawings. Moreover, in this application, reference is made to many blood parameters. Some references that have common shorthand designations are referenced through such shorthand designations. For example, as used herein, HbCO designates carboxyhemoglobin, HbMet designates methemoglobin, and Hbt designates total hemoglobin. Other shorthand designations such as COHb, MetHb, and tHb are also common in the art for these same constituents. These constituents are generally reported herein in terms of a percentage, often referred to as saturation, relative concentration or fractional saturation. Total hemoglobin is generally reported as a concentration in g/dL. The use of the particular shorthand designators presented in this application does not restrict the term to any particular manner in which the designated constituent is reported.

FIG. **1** illustrates a block diagram of an exemplary embodiment of a patient monitoring system **100**. As shown in FIG. **1**, the system **100** includes a patient monitor **102** comprising a processing board **104** and a host instrument **108**. The processing board **104** communicates with a sensor **106** to receive one or more intensity signal(s) indicative of one or more parameters of tissue of a patient. The processing board **104** also communicates with a host instrument **108** to display determined values calculated using the one or more intensity signals. According to an embodiment, the board **104** comprises processing circuitry arranged on one or more printed circuit boards capable of installation into the monitor **102**, or capable of being distributed as some or all of one or more OEM components for a wide variety of host instruments monitoring a wide variety of patient information. In an embodiment, the processing board **102** comprises a sensor interface **110**, a digital signal processor and signal extractor ("DSP" or "processor") **112**, and an instrument manager **114**. In general, the sensor interface **110** converts digital control signals into analog drive signals capable of driving sensor emitters, and converts composite analog intensity signal(s) from light sensitive detectors into digital data.

In an embodiment, the sensor interface **110** manages communication with external computing devices. For example, in an embodiment, a multipurpose sensor port (or input/output port) is capable of connecting to the sensor **106** or alternatively connecting to a computing device, such as a personal computer, a PDA, additional monitoring equipment or networks, or the like. When connected to the computing device, the processing board **104** may upload various stored data for, for example, off-line analysis and diagnosis. The stored data may comprise trend data for any one or more of the measured parameter data, plethysmograph waveform data acoustic sound waveform, or the like. Moreover, the processing board **104** may advantageously download from the computing device various upgrades or executable programs, may perform diagnosis on the hardware or software of the monitor **102**. In addition, the processing board **104** may advantageously be used to view and examine patient data, including raw data, at or away from a monitoring site, through data uploads/downloads, or network connections, combinations, or the like, such as for customer support purposes including software maintenance, customer technical support, and the like. Upgradable sensor ports are disclosed in copending U.S. application Ser. No. 10/898,680, filed on Jul. 23, 2004, titled "Multipurpose Sensor Port," incorporated by reference herein.

As shown in FIG. **1**, the digital data is output to the DSP **112**. According to an embodiment, the DSP **112** comprises a processing device based on the Super Harvard ARChitecture ("SHARC"), such as those commercially available from Analog Devices. However, a skilled artisan will recognize from the disclosure herein that the DSP **112** can comprise a wide variety of data and/or signal processors capable of executing programs for determining physiological parameters from input data. In particular, the DSP **112** includes program instructions capable of receiving multiple channels of data related to one or more intensity signals representative of the absorption (from transmissive or reflective sensor systems) of

a plurality of wavelengths of emitted light by body tissue. In an embodiment, the DSP **112** accepts data related to the absorption of eight (8) wavelengths of light, although an artisan will recognize from the disclosure herein that the data can be related to the absorption of two (2) to sixteen (16) or more wavelengths.

FIG. **1** also shows the processing board **104** including the instrument manager **114**. According to an embodiment, the instrument manager **114** may comprise one or more microcontrollers controlling system management, including, for example, communications of calculated parameter data and the like to the host instrument **108**. The instrument manager **114** may also act as a watchdog circuit by, for example, monitoring the activity of the DSP **112** and resetting it when appropriate.

The sensor **106** may comprise a reusable clip-type sensor, a disposable adhesive-type sensor, a combination sensor having reusable and disposable components, or the like. Moreover, an artisan will recognize from the disclosure herein that the sensor **106** can also comprise mechanical structures, adhesive or other tape structures, Velcro wraps or combination structures specialized for the type of patient, type of monitoring, type of monitor, or the like. In an embodiment, the sensor **106** provides data to the board **104** and vice versa through, for example, a patient cable. An artisan will also recognize from the disclosure herein that such communication can be wireless, over public or private networks or computing systems or devices, or the like.

As shown in FIG. **1**, the sensor **106** includes a plurality of emitters **116** irradiating the body tissue **118** with differing wavelengths of light, and one or more detectors **120** capable of detecting the light after attenuation by the tissue **118**. In an embodiment, the emitters **116** comprise a matrix of eight (8) emission devices mounted on a flexible substrate, the emission devices being capable of emitting eight (8) differing wavelengths of light. In other embodiments, the emitters **116** may comprise twelve (12) or sixteen (16) emitters, although other numbers of emitters are contemplated, including two (2) or more emitters. As shown in FIG. **1**, the sensor **106** may include other electrical components such as, for example, a memory device **122** comprising an EPROM, EEPROM, ROM, RAM, microcontroller, combinations of the same, or the like. In an embodiment, other sensor components may include a temperature determination device **123** or other mechanisms for, for example, determining real-time emission wavelengths of the emitters **116**.

The memory **122** may advantageous store some or all of a wide variety data and information, including, for example, information on the type or operation of the sensor **106**; type or identification of sensor buyer or distributor or groups of buyer or distributors, sensor manufacturer information, sensor characteristics including the number of emitting devices, the number of emission wavelengths, data relating to emission centroids, data relating to a change in emission characteristics based on varying temperature, history of the sensor temperature, current, or voltage, emitter specifications, emitter drive requirements, demodulation data, calculation mode data, the parameters for which the sensor is capable of supplying sufficient measurement data (e.g., HpCO, HpMet, HbT, or the like), calibration or parameter coefficient data, software such as scripts, executable code, or the like, sensor electronic elements, whether the sensor is a disposable, reusable, multisite, partially reusable, partially disposable sensor, whether it is an adhesive or non-adhesive sensor, whether the sensor is a reflectance, transmittance, or transreflectance sensor, whether the sensor is a finger, hand, foot, forehead, or ear sensor, whether the sensor is a stereo sensor or a two-headed sensor, sensor life data indicating whether some or all sensor components have expired and should be replaced, encryption information, keys, indexes to keys or hash functions, or the like, monitor or algorithm upgrade instructions or data, some or all of parameter equations, information about the patient, age, sex, medications, and other information that may be useful for the accuracy or alarm settings and sensitivities, trend history, alarm history, or the like. In an embodiment, the monitor may advantageously store data on the memory device, including, for example, measured trending data for any number of parameters for any number of patients, or the like, sensor use or expiration calculations, sensor history, or the like.

FIG. **1** also shows the patient monitor **102** including the host instrument **108**. In an embodiment, the host instrument **108** communicates with the board **104** to receive signals indicative of the physiological parameter information calculated by the DSP **112**. The host instrument **108** preferably includes one or more display devices **124** capable of displaying indicia representative of the calculated physiological parameters of the tissue **118** at the measurement site. In an embodiment, the host instrument **108** may advantageously comprise a handheld housing capable of displaying one or more of a pulse rate, plethysmograph data, perfusion quality such as a perfusion quality index ("PI™"), signal or measurement quality ("SQ"), values of blood constituents in body tissue, including for example, SpO_2, HbCO, HbMet, Hbt, or the like. In other embodiments, the host instrument **108** is capable of displaying values for one or more of Hbt, Hb, blood glucose, bilirubin, or the like. The host instrument **108** may be capable of storing or displaying historical or trending data related to one or more of the measured values, combinations of the measured values, plethysmograph data, or the like. The host instrument **108** also includes an audio indicator **126** and user input device **128**, such as, for example, a keypad, touch screen, pointing device, voice recognition device, or the like.

In still additional embodiments, the host instrument **108** includes audio or visual alarms that alert caregivers that one or more physiological parameters are falling below predetermined safe thresholds. The host instrument **108** may include indications of the confidence a caregiver should have in the displayed data. In a further embodiment, the host instrument **108** may advantageously include circuitry capable of determining the expiration or overuse of components of the sensor **106**, including, for example, reusable elements, disposable elements, or combinations of the same.

Although described in terms of certain embodiments, other embodiments or combination of embodiments will be apparent to those of ordinary skill in the art from the disclosure herein. For example, the monitor **102** may comprise one or more monitoring systems monitoring parameters, such as, for example, vital signs, blood pressure, ECG or EKG, respiration, glucose, bilirubin, or the like. Such systems may combine other information with intensity-derived information to influence diagnosis or device operation. Moreover, the monitor **102** may advantageously include an audio system, preferably comprising a high quality audio processor and high quality speakers to provide for voiced alarms, messaging, or the like. In an embodiment, the monitor **102** may advantageously include an audio out jack, conventional audio jacks, headphone jacks, or the like, such that any of the display information disclosed herein may be audiblized for a listener. For example, the monitor **102** may include an audible transducer input (such as a microphone, piezoelectric sensor, or the like) for collecting one or more of heart sounds, lung sounds, trachea sounds, or other body sounds and such

sounds may be reproduced through the audio system and output from the monitor **102**. Also, wired or wireless communications (such as Bluetooth or WiFi, including IEEE 801.11a, b, or g), mobile communications, combinations of the same, or the like, may be used to transmit the audio output to other audio transducers separate from the monitor **102**.

For example, patterns or changes in the continuous noninvasive monitoring of intensity-derived information may cause the activation of other vital sign measurement devices, such as, for example, blood pressure cuffs.

FIG. **2** illustrates a perspective view of an exemplary handheld noninvasive multi-parameter patient monitor **200**, such as, for example, the patient monitor **102** of FIG. **2**. Patient monitors **200** exhibiting combinations of many of the features described herein are advantageously commercially available from Masimo under the brand name "Rad 57c." As shown in FIG. **1**, the monitor **200** includes a patient cable connector **202** capable of mechanical mating with a patient cable to establish communication between the board **104** and the sensor **106**. In an embodiment, the connector **202** comprises a multipurpose cable connector such as that disclosed in the incorporated U.S. application Ser. No. 10/898,680, titled "Multipurpose Sensor Port," disclosing communication between the board **104** and an external computing device.

The monitor **200** also comprises a HbCO indicator **204** advantageously providing a visual queue that a HbCO capable sensor is properly connected through the connector **202**. For example, the HbCO indicator **204** may advantageously activate when a sensor is connected that communicates sufficient information to determine HbCO, such as, for example, a sensor capable of emitting sufficient different wavelengths of light, a sensor storing sufficient data on the memory **122**, a sensor having appropriate encryption data or key, combinations of the same, or the like. For example, in an embodiment, the processor **112** may receive information from a memory **122** indicating a number of available LED wavelengths for the attached sensor. Based on the number of wavelengths, or other information stored on the memory **122**, the processor **112** may determine whether an HbCO-ready sensor has been attached to the monitor **200**. An artisan will also recognize from the disclosure herein that the HbCO indicator **204** may advantageously comprise a HbMet indicator, Hbt indicator, or the like, which activates to a predetermined color associated with a parameter, or any color, or deactivates the same, to convey a type of attached sensor. Moreover, the artisan will recognize from the disclosure herein other parameters that may use other sensor components and the monitor **200** may include indicators capable of indicating communication with those types of sensors.

In an embodiment, the monitor **200** may also audibly indicate the type of sensor connected. For example, the monitor **200** may emit predetermined number or frequency of beeps associated with recognition of a particular sensor, a particular manufacturer, failure to recognize the sensor, or the like. Moreover, the sensor type may be indicative of the componentry, such as, for example, whether the sensor produces sufficient data for the determination of HbCO, HbMet, Hbt and SpO_2, SpO_2 only, SpO_2 and HbMet, any combination of the foregoing or other parameters, or the like. Additionally, the sensor type may be indicative of specific sensors designed for a type of patient, type of patient tissue, or the like. In other embodiments, the monitor **200** may announce the type of connector through speaker **236**.

An artisan will also recognize from the disclosure herein that other mechanical (such as keys), electrical, or combination devices may inform the monitor **200** of the type of attached sensor. In an embodiment, the processor **112** also may select to drive less emitters that are currently available, such as, for example, in the presence of low noise and when power consumption is an issue.

The monitor **200** also comprises a multi-mode display **206** capable of displaying, for example, measurements of SpO_2 and HbCO (or alternatively, HbMet). In an embodiment, the display **206** has insufficient space or display real estate to display the many parameters capable of being measured by the monitor **200**. Thus, the multi-mode display **206** may advantageously cycle through two or more measured parameters in an area common to both parameters even when shifted. In such embodiments, the monitor **200** may also advantageously include parameter indicators **208**, **210**, providing additional visual queues as to which parameter is currently displayed. In an embodiment, the display may also cycle colors, flash rates, or other audio or visual queues providing readily identifiable information as to which measured parameter is displayed. For example, when the multi-mode display **206** displays measured values of SpO_2 that are normal, the numbers may advantageously appear in green, while normal measured values of HbCO may advantageously appear in orange, and normal measured values of HbMet may appear in blue. Moreover, in an embodiment, the display **206** flashes at a predefined rate when searching for saturation and at another predefined rate when a signal quality is below a predetermined threshold.

The monitor **200** also comprises a HbCO bar **212** where in an embodiment a plurality of LED's activate from a bottom toward a top such that the bar "fills" to a level proportional to the measured value. For example, the bar **212** is lowest when the dangers from carbon monoxide poisoning are the least, and highest when the dangers are the greatest. The bar **212** includes indicia **214** that provide an indication of the severity of carbon monoxide saturation in a patient's blood. As shown in FIG. **2**, the bar **212** and the indicia **214** continuously indicate the concentration of HbCO in about 5% increments. The indicia **214** indicate a measurement of HbCO saturation percentage between about 0 and about 50% with a granularity of about 5%. However, an artisan will also recognize from the disclosure herein a wide variety of ranges and granularities could be used, the indicia **214** could be electronically displayed in order to straightforwardly increase or decrease resolution, or the like. For example, HbCO may advantageously be displayed with greater resolution than ± about %5 in a lower portion of the scale. For example, an HbCO bar may advantageously include a scale of about <3%, about 6%, about 9%, about 12%, about 15%, about 20%, about 25%, about 30%, about 35%, and about >40%.

As is known in the art, carbon monoxide in the blood can lead to serious medical issues. For example and depending upon the particular physiology of a patient, about 10% carbon monoxide saturation can lead to headaches, about 20% can lead to throbbing headaches, or dyspnea on exertion, about 30% can lead to impaired judgment, nausea, dizziness and/or vomiting, visual disturbance, or fatigue, about 40% can lead to confusion and syncope, and about 50% and above can lead to comas, seizures, respiratory failure and even death.

In an embodiment, the bar **212** is the same or similar color as the multi-mode display **206** when displaying HbCO. In other embodiments, the bar **212** is lowest and green when the dangers from carbon monoxide poisoning are the least, and highest and red when the dangers are the greatest. In an embodiment, as HbCO increases, the entire bar **212** may advantageously change color, such as, for example, from green to red, to provide a clear indication of deepening severity of the condition. In other embodiments, the bar **212** may advantageously blink or flash, an audio alarm may beep or

provide a continuation or rise in pitch or volume, or the like to alert a caregiver of deepening severity. Moreover, straightforward to complex alarm rules may be implemented to reduce false alarms based on, for example, knowledge of the physiological limitations on the rate of change in HbCO or the like.

Additionally, the monitor **200** may be capable of storing and outputting historical parameter data, display trend traces or data, or the like. Although the foregoing bar **212** has been described in terms of certain preferred embodiments, other embodiments will be apparent to those of ordinary skill in the art from the disclosure herein.

FIG. **2** also shows the monitor **200** including a pulse display **216** displaying measured pulse rate in beats per minute ("BPM"). In an embodiment, the display **212** flashes when searching for a pulse. The pulse display **216** advantageously displays measured pulse rates from about zero (0) to about two hundred and forty (240) BPM. Moreover, when the measured pulse rates are considered normal, the pulse display **216** is advantageously green. Similar to other displays associated with the monitor **200**, the pulse display **216** may employ a variety of color changes, audio alarms, or combinations of the same to indicate measured BPM below predetermined safe thresholds. In an embodiment, the pulse rate display **216** displays the measured pulse rate during the display of SpO_2 and displays message data during the display of other parameters. For example, during the display of HbCO, the display **216** may advantageously display the term "CO." In an embodiment, the display of the message data may be in the same or similar color as the other displays. For example, in an embodiment, the multi-mode display **206**, the bar **212**, and the pulse display **216** may all display data or messages in orange when the multi-mode display **206** displays measured HbCO values.

FIG. **2** also illustrates the monitor **200** comprising user input keys **218**, including a HbCO button **220**, mode/enter button **222**, next button **224**, power on/off button **226**, up/down button **228**, and alarm silence button **230**. In an embodiment, activation of the HbCO button **220** toggles the measured value displayed in the multi-mode display **206**. For example, activation of the HbCO button **220** toggles the multi-mode display **206** from displaying measured values of SpO_2 to HbCO for about ten (10) seconds. Activation of the mode/enter button **222** or the next button **224** during the ten (10) second period returns the multi-mode display **206** back to SpO_2. A skilled artisan will also recognize that activation of the HbCO button **220** may advantageously toggle through a plurality of measured values, and that such values may be displayed for short segments and then return to SpO_2, may remain displayed until further activation of the button **220**, or the like.

Activation of the mode/enter button **222** cycles through various setup menus allowing a caregiver to select or activate certain entries within the menu setup system, including alarm threshold customizations, or the like. Activation of the next button **224** can move through setup options within the menu setup system and in an embodiment is not active during normal patient monitoring. For example, a caregiver may activate the mode/enter button **222** and the next button **224** to specify high and low alarm thresholds for one or more of the measured parameters, to specify device sensitivity, trend settings, display customizations, color code parameters, or the like. In an embodiment, the high alarm setting for SpO_2 can range from about two percent (2%) to about one hundred percent (100%) with a granularity of about one percent (1%). The low alarm setting for SpO_2 can range from about one percent (1%) to about one hundred percent (100%) with a granularity of about one percent (1%). Moreover, the high alarm setting for pulse rate can range from about thirty (30) BPM to about two hundred and forty (240) BPM with a granularity of about five (5) BPM. The low alarm setting for pulse rate can range from about twenty five (25) BPM to about two hundred and thirty five (235) BPM with a granularity of about five (5) BPM. Other high and low ranges for other measured parameters will be apparent to one of ordinary skill in the art from the disclosure herein.

In a further embodiment, a caregiver may activate the mode/enter button **222** and the next button **224** to specify device sensitivity, such as, for example, device averaging times, probe off detection, whether to enable fast saturation calculations, or the like. Various embodiments of fast saturation calculations are disclosed in U.S. patent application Ser. No. 10/213,270, filed Aug. 5, 2002, titled "Variable Indication Estimator" and incorporated by reference herein. Using the menus, a caregiver may also advantageously enter appropriate information governing trend collection on one or more of the measured parameters, input signals, or the like.

FIG. **2** also shows the power on/off button **226**. Activation of the power on/off button **226** activates and deactivates the monitor **200**. In an embodiment, press-and-hold activation for about two (2) seconds shuts the monitor **200** off. In an additional embodiment, activation of the on/off button **226** advantageously initiates detection of a type of attached sensor. For example, activation of the on/off button **226** may advantageously cause the monitor **200** to read information from a memory on an attached sensor and determine whether sufficient wavelengths exist on the sensor to determine one or more the physiological parameters discussed in the foregoing.

An artisan will recognize from the disclosure herein that the on/off button **226** may advantageously cause an electronic determination of whether to operate in at powers consisted with the U.S. (60 Hz) or another nationality (50 Hz). In an embodiment, such automatic determination and switching is removed from the monitor **200** in order to reduce a likelihood of problematic interfering crosstalk caused by such power switching devices.

Activation of the up/down button **228** may advantageously adjust the volume of the pulse beep tone. Additionally, activation of the up/down button **228** within the menu setup system, causes the selection of values with various menu options.

Moreover, activation of the alarm silence button **230** temporarily silences audio alarms for a predetermined period, such as, for example, about one hundred and twenty (120) seconds. A second activation of the alarm silence button **230** mutes (suspends) the alarm indefinitely, while a third activation returns the monitor **200** to standard alarm monitoring. FIG. **2** also shows the alarm silence button **230** includes an alarm silenced indicator **232**. The alarm silenced indicator **232** may advantageously flash to indicate one or more alarms are temporarily silenced, may illuminate solid to indicate the alarms have been muted, or the like. Moreover, an artisan will recognize from the disclosure herein a wide variety of alarm silencing methodologies.

The monitor **200** also includes a battery level indicator **234** indicating remaining battery life. In the illustrated embodiment, four LED's indicate the status of the battery by incrementally deactivating to indicate proportionally decreasing battery life. In an embodiment, the four LED's may also change color as the battery charge decreases, and the final LED may begin to flash to indicate that the caregiver should replace the batteries.

FIG. **2** also shows the monitor **200** including an audio transducer or speaker **236**. The speaker **236** advantageously

provides audible indications of alarm conditions, pulse tone and feedback for key-presses, or the like. Moreover, the monitor **200** includes a low signal quality indicator ("SQ" or "SIQ™") **238**. The signal IQ indicator **238** activates to inform a caregiver that a measured value of the quality of the incoming signal is below predetermined threshold values. For example, in an embodiment, the measured value for signal IQ is at least partially based on an evaluation of the plethysmograph data's correspondence to predetermined models or characteristics of physiological signals. In an embodiment, the signal IQ indicator **238** output may be associated with the displayed parameter. For example, the output may be associated with one threshold for the display of SpO_2 and another for the display of other parameter data.

The monitor **200** also comprises a perfusion quality index ("PI™") bar **240** (which quantifies the measure of perfusion of the patient) where in an embodiment a plurality of LED's activate from a bottom toward a top such that the bar "fills" to a level proportional to the measured value. In one embodiment, the PI™ bar **240** shows a static value of perfusion for a given time period, such as, for example, one or more pulses. In another embodiment, or functional setting, the PI™ bar **240** may advantageously pulse with a pulse rate, may hold the last reading and optionally fade until the next reading, may indicate historical readings through colors or fades, or the like. Additionally, the PI™ bar **240** may advantageously change colors, flash, increasingly flash, or the like to indicate worsening measured values of perfusion.

The PI™ bar **240** can be used to simply indicate inappropriate occlusion due, for example, to improper attachment of the sensor **106**. The PI™ bar **240** can also be used as a diagnostic tool during low perfusion for the accurate prediction of illness severity, especially in neonates. Moreover, the rate of change in the PI™ bar **240** can be indicative of blood loss, sleep arousal, sever hypertension, pain management, the presence or absence of drugs, or the like. According to one embodiment, the PI™ bar **240** values may comprise a measurement of the signal strength of the arterial pulse as a percentage of the total signal received. For example, in one preferred embodiment, the alternating portion of at least one intensity signal from the sensor **106** may advantageously be divided by the static portion of the signal. For example, an infrared intensity signal may advantageously be used as it is less subjective to noise.

In an embodiment, a measurement below about 1.25% may indicate medical situations in need of caregiver attention, specifically in monitored neonates. Because of the relevance of about 1.25%, the PI™ bar **240** may advantageously include level indicia **242** where the indicia **242** swap sides of the PI™ bar **240**, thus highlighting any readings below about that threshold. Moreover, behavior of the PI™ bar **240**, as discussed above, may advantageously draw attention to monitored values below such a threshold.

As discussed above, the monitor **200** may include output functionality that outputs, for example, trend perfusion data, such that a caregiver can monitor measured values of perfusion over time. Alternatively or additionally, the monitor **200** may display historical trace data on an appropriate display indicating the measured values of perfusion over time. In an embodiment, the trend data is uploaded to an external computing device through, for example, the multipurpose sensor connector **202** or other input output systems such as USB, serial or parallel ports or the like.

The monitor **200** also includes an alarm indicator **244** capable of providing visual queues of the status of one or more of the measured parameters. For example, the alarm indicator **244** may advantageously be green when all of the measured parameters are within normal conditions, may gradually fade to red, may flash, increasing flash, or the like, as one or more of the measured values approaches or passes predetermined thresholds. In an embodiment, the alarm indicator **244** activates when any parameter falls below an associated threshold, thereby advantageously informing a caregiver that perhaps a nondisplayed parameters is at an alarm condition. In another embodiment, the alarm indicator **244** may indicate the status of the parameter displayed on the multi-mode display **206**. In an embodiment, the speaker **236** may sound in conjunction with and/or in addition to the indicator **244**. Moreover, in an embodiment, an alarming parameter may automatically be displayed, may be emphasized, flashed, colored, combinations of the same or the like to draw a user's attention to the alarming parameter.

Although the foregoing invention has been described in terms of certain preferred embodiments, other embodiments will be apparent to those of ordinary skill in the art from the disclosure herein.

FIG. **3** illustrates an exemplary display of the patient monitor **200**. As shown in FIG. **3**, the display includes the multi-mode display **206**, the pulse rate display **216**, parameter indicators **208**, **210**, the HbCO bar **212** and indicator **204**, the PI™ bar **240**, and the alarm indicator **244**. In an embodiment, the multi-mode display **206** and the pulse rate display **216** each comprise a plurality of seven segment displays **302** capable of displaying alpha-numeric information. As disclosed in the foregoing, the exemplary display may advantageously include color-coded parameter displays. Moreover, the exemplary display may include color progressions, flashing, flashing progressions, audible alarms, audible progressions, or the like, indicating worsening measured values of physiological data. In addition, in an embodiment, some or all of the displays may flash at a first rate to indicate attempts to acquire data when actual measured values are unavailable. Moreover, some or all of the display may flash at a second rate to indicate low signal quality where confidence is decreasing that the measured values reflect actual physiological conditions.

FIG. **4** illustrates the display of FIG. **3** showing measured values of SpO_2, BPM, perfusion, and type of sensor, according to an exemplary embodiment of the patient monitor of FIG. **1**. As shown in FIG. **4**, the multi-mode display **206** is displaying a percentage value of SpO_2, and the pulse rate display **216** is displaying a pulse rate in beats per minute. Accordingly, the parameter indicator **210** is activated to confirm the display of measured values of SpO_2. As disclosed in the foregoing, in an embodiment, the multi-mode display **206** is red, indicating blood oxygen measurements while the pulse rate display **216** is green, indicating normal values of a patient's pulse.

FIG. **4** also shows the PI™ bar **240** almost fully activated, representing good perfusion. In addition, the HbCO indicator **204** is showing communication with a sensor producing insufficient data to determine measured values of additional parameters, such as, HbCO. In an embodiment, such sensors may comprise sensors capable of emitting light at about two (2) different wavelengths, may comprise sensors with insufficient data stored on a memory associated therewith, or the like.

FIG. **5** illustrates the display of FIG. **3** showing measured values of HbCO, perfusion, and type of sensor, according to an exemplary embodiment of the patient monitor of FIG. **1**. As shown in FIG. **5**, the multi-mode display **206** is displaying a percentage value of HbCO, and the pulse rate display **216** is displaying an appropriate message indicating the HbCO measurement, such as, for example, "CO". Also, the multi-mode display **206** has shifted the data to the left to quickly and

efficiently indicate that the displayed parameter is other than SpO_2. Accordingly, the parameter indicator **208** is also activated to confirm the display of measured values of HbCO. As disclosed in the foregoing, in an embodiment, the multi-mode display **206** and pulse rate display message **216** are orange.

FIG. **5** also shows the PI™ bar **240** almost fully activated, representing good perfusion. In addition, the activation of the HbCO indicator **204** represents communication with a sensor capable of producing sufficient data to determine measured values of HbCO. In an embodiment, such sensors may comprise sensors capable of emitting light at about eight (8) or more different wavelengths; however, such sensors may comprise about two (2) or more different wavelengths. Moreover, such sensors may have appropriate data stored on a memory associated therewith, or the like. FIG. **5** also shows the HbCO measurement being about 20% (as illustrated on the HbCO bar **212** and multi-mode display **206**) thereby indicating a potentially dangerous situation that if exacerbated, will become quite problematic. Therefore, the alarm indicator **244** is also activated, and in some embodiments, the speaker **236** as well.

FIG. **6** illustrates the display of FIG. **3** showing measured values of SpO_2, HbCO, BPM, perfusion, and type of sensor, according to an exemplary embodiment of the patient monitor of FIG. **1**. In contrast to FIG. **4**, FIG. **6** shows that the monitor **200** is communicating with a sensor capable of producing sufficient data to determine measured values of HbCO, even though the displayed values are that of SpO_2 and BPM. Thus, FIG. **6** shows the activation of the HbCO indicator **204**, and the continuous monitoring of HbCO by the HbCO bar **212**. FIG. **6** also shows a high value of HbCO, and therefore, the indication of an alarm condition by activation of the alarm indicator **244**. In an embodiment, upon determination of an alarm condition on a nondisplayed parameter, the monitor **200** may advantageously provide an alarm indication through speaker and alarm indicator activation, automatic toggle to the nondisplayed parameter on the multi-mode display **206** for a defined or undefined time, or the like.

FIG. **7** illustrates a top elevation view of an exemplary handheld noninvasive multi-parameter patient monitor **700** capable of displaying at least HbCO and HbMet, such as, for example, the patient monitor of FIG. **1**. Patient monitors exhibiting combinations of many of the features described herein are advantageously commercially available from Masimo under the brand name "Rad 57 cm." As shown in FIG. **7**, the monitor **700** comprises a monitor similar to monitor **200** disclosed with reference to FIG. **2**. Moreover, monitor **700** further includes a multi-mode display **706** capable of displaying, for example, measurements of HbMet and BPM. In an embodiment, the display **706** has insufficient space or display real estate to display the many parameters capable of being measured by the monitor **700**. Thus, the multi-mode display **706** may advantageously cycle through two or more measured parameters. In such embodiments, the monitor **700** may also advantageously include parameter indicators **708**, **710**, providing additional visual queues as to which parameter is currently displayed. In an embodiment, the display **706** may also cycle colors, flash rates, or other audio or visual queues providing readily identifiable information as to which measured parameter is displayed. For example, when the multi-mode display **706** displays measured values of BPM that are normal, the numbers may advantageously appear in green, while normal measured values of HbMet may appear in blue. Moreover, in an embodiment, the display **706** may flash at a predefined rate when searching for saturation and at another predefined rate when a signal quality is below a predetermined threshold.

FIG. **7** also illustrates the monitor **700** comprising user input keys **718**, including an HbCO/HbMet button **220**. In an embodiment, activation of the HbCO/HbMet button **720** toggles the measured value displayed in the multi-mode display **706**. For example, activation of the HbCO/HbMet button **720** toggles the multi-mode display **206** from displaying measured values of SpO_2 and BPM, to HbCO and HbMet for about ten (10) seconds. Activation of the mode/enter button **222** or the next button **224** during the ten (10) second period returns the multi-mode display **706** back to SpO_2 and BPM. A skilled artisan will also recognize that activation of the HbCO/HbMet button **720** may advantageously toggle through a plurality of measured values, and that such values may be displayed for short segments and then return to SpO_2 and BPM, may remain displayed until further activation of the button **720**, or the like.

The monitor **700** also comprises a coarser indication of HbMet through an HbMet bar **740**. In an embodiment, a plurality of LED's activate from a bottom toward a top such that the bar "fills" to a level proportional to the measured value, with increments at about 0.5%, about 1%, about 2%, about 3%, about 4%, about 5%, about 7.5%, about 10%, about 15% and greater than about 20%, although an artisan will recognize from the disclosure herein other useful delineations. Additionally, the HbMet bar **740** may advantageously change colors, flash, increasingly flash, or the like to indicate worsening measured values of perfusion.

Although disclosed with reference to the HbMet bar **740**, and artisan will recognize from the disclosure herein other coarse or even gross indications of HbMet, or any measured parameter. For example, a single LED may advantageously show green, yellow, and red, to indicate worsening coarse values of HbMet. Alternatively, a single LED may simply light to indicate an alarm or approaching alarm condition.

FIG. **8** illustrates an exemplary display of the patient monitor **700** of FIG. **7**. As shown in FIG. **8**, the display includes the multi-mode displays **206**, **706**, parameter indicators **208**, **210**, **708**, **710**, the HbCO bar **212** and indicator **204**, the HbMet bar **740**, and the alarm indicator **244**. In an embodiment, the multi-mode display **706** is similar to multi-mode display **206**, comprising a plurality of seven segment displays **302** capable of displaying alpha-numeric information, and capable of altering its display characteristics or aspects in a wide variety of configurations discussed with reference to the display **206**.

FIG. **9** illustrates the display of FIG. **8** showing measured values of SpO_2, BPM, HbCO, HbMet, and type of sensor according to an exemplary embodiment of the patient monitor of FIG. **1**. FIG. **9** also shows the HbMet bar **740** near the bottom and corresponding to about 1%, representing acceptable HbMet, while the HbCO bar **212** hovers at a dangerous near 20%. In addition, the HbCO indicator **204** is showing communication with a sensor producing sufficient data to determine measured values of additional parameters, such as, HbMet, HbCO or the like. In an embodiment, such sensors may comprise sensors capable of emitting light of more than two (2) different wavelengths, preferably more than four (4) different wavelengths, and more preferably eight (8) or more different wavelengths.

FIG. **10** illustrates the display of FIG. **8** showing measured values of HbCO, HbMet, and type of sensor according to an exemplary embodiment of the patient monitor of FIG. **1**. As shown in FIG. **10**, the multi-mode display **706** is displaying a percentage value of HbMet that is shifted using the parameter indicator **708**. The data has been advantageously shifted to the left to quickly and efficiently indicate that the displayed parameter is other than BPM. Accordingly, the parameter indicator **708** is also activated to confirm the display of mea-

sured values of HbMet. As disclosed in the foregoing, in an embodiment, the multi-mode display **706** is blue.

FIG. **10** also shows the HbMet bar **740** nearly empty, representing acceptable HbMet. In addition, the activation of the HbCO indicator **204** represents communication with a sensor capable of producing sufficient data to determine measured values of HbCO. In an embodiment, such sensors may have appropriate data stored on a memory associated therewith, or the like. FIG. **10** also shows the HbCO measurement being about 20% (as illustrated on the HbCO bar **212** and multi-mode display **206**) thereby indicating a potentially dangerous situation that if exacerbated, will become quite problematic. Therefore, the alarm indicator **244** is also activated, and in some embodiments, the speaker **236** as well.

FIG. **11**A illustrates a perspective view of an exemplary noninvasive multi-parameter patient monitor **1100**, such as, for example, the patient monitor of FIG. **1**. Moreover, FIGS. **11**B-**11**E illustrate exemplary display screens of the patient monitor of FIG. **11**A. As shown in FIGS. **11**A-**11**B, an embodiment of the monitor **1100** includes a display **1101** showing a plurality of parameter data. For example, the display may advantageously comprise a CRT or an LCD display including circuitry similar to that available on oximeters commercially available from Masimo Corporation of Irvine, Calif. sold under the name Radical™, and disclosed in the U.S. patents referenced above and incorporated above. However, an artisan will recognize from the disclosure herein many commercially available display components capable of displaying multiple parameter data along with the ability to display graphical data such as plethysmographs, trend traces, and the like.

In an embodiment, the display includes a measured value of SpO_2 **1102**, a measured value of pulse rate **1104** in BPM, a plethysmograph **1106**, a measured value of HbCO **1108**, a measured value of HbMet **1110**, a measured value of a perfusion quality **1112**, a measured value of Hbt **1114**, and a derived value of fractional saturation "$SpaO_2$" **116**. In an embodiment, $SpaO_2$ comprises HbO_2 expressed as a percentage of the four main hemoglobin species, i.e., HbO_2, Hb, HbCO, and HbMet.

In an embodiment, one or more of the foregoing parameter includes trending or prediction indicators **1118** showing the current trend or prediction for that corresponding parameter. In an embodiment, the indicators **1118** may advantageously comprise an up arrow, a down arrow, and a hyphen bar to indicate up trending/prediction, down trending/prediction, or neutral trending/prediction.

FIG. **11**C illustrates an exemplary display screen showing trend graph **1140** including trend line **1142** for HbMet. In an embodiment, the trend line **1142** may be advantageously colored for quick straightforward recognition of the trending parameter, may be associated with any one or more of the foregoing alarm attributes, may include trending lines for other parameters, or the like. The display screen also shows trending directional indicators **1142**, **1144** for many of the displayed physiological parameters. In an embodiment, the directional indicators **1142**, **1144** may advantageously comprises arrows showing the recent trend, predicted trend, user-customizable trend, combinations thereof, or the like for the associated parameters. In an embodiment, the directional indicators **1142**, **1144** comprises an up arrow indicating a rising trend/predicted trend, a middle bar indicating a somewhat stable trend/predicted trend, and a down arrow indicating a lowering trend/predicted trend. An artisan will recognize a wide variety of other directional indicators **1142**, **1144** from the disclosure herein.

FIG. **11**D shows an exemplary display screen in vertical format. Such vertical format could be user actuated or based on a gravity switch. FIGS. **11**E-**11**F illustrate additional displays of various physiological parameters similar to those discussed in the foregoing. being As shown in FIG. **11**G, the display includes a measured value of SpO_2 **1162**, a measured value of pulse rate **1164** in BPM, a plethysmograph **1166**, a HbCO bar **1168**, and a HbMet bar **1170**. In an embodiment, the HbCO bar **1168** and HbMet bar **1170** may advantageously behave the same or similarly to the HbCO bar **212** and HbMet bar **712**. Moreover, similar bars may advantageously display any of the physiological parameters discussed herein using display indicia appropriate to that parameter. For example, a SpO_2 or $SpaO_2$ bar may advantageously range from about 0% to about 100%, and more preferably range from about 50% to about 100%, while a Hbt bar may advantageously range from about 0 to about 30.

Moreover, similar to the disclosure above, the measured value of SpO_2 **1162** may advantageously toggle to measured values of HbCO, HbMet, Hbt, or the like based on, for example, actuation of user input keys, or the like.

In addition to the foregoing, the display may also include graphical data showing one or more color-coded or other identifying indicia for traces of trend data. Moreover, other graphical presentations may advantageously provide readily identifiable indications of monitored parameters or combinations of monitored parameters of the patient. For example, in an embodiment, the display includes a $SpaO_2$ graph **1172**. The $SpaO_2$ graph **1172** plots SpO_2 as a function of other blood analytes (1-$SpaO_2$), where $SpaO_2$ comprises HbO_2 expressed as a percentage of the four main hemoglobin species, i.e., HbO_2, Hb, HbCO, and HbMet. Thus, as shown in FIG. **11**C, as the slope of the displayed line or arrow increases, the caregiver can readily note that the majority of hemoglobin carriers are being used to carry oxygen, and not, for example, harmful carbon monoxide. On the other hand, as the slope decreases, the caregiver can readily and advantageously note that the number of hemoglobin species available to carry oxygen is decreasing, regardless of the current value of SpO_2. Moreover, the length of the arrow or line also provides an indication of wellness, e.g., the higher the line the more oxygen saturation, the lower the line, the more likely there may be desaturation event, or the like.

Thus, the $SpaO_2$ graph **1172** provides the caregiver with the ability to recognize that even though the measured value of SpO_2 may be within acceptable ranges, there are potentially an unacceptable number of hemoglobin carriers unavailable for carrying oxygen, and that other potential problems may exist, such as, for example, harmful carbon monoxide levels, or the like. In an embodiment, various alarm conditions may cause the graph **1172** to change color, flash, or any combination of alarm indications discussed in the foregoing. Moreover, FIG. **11** illustrates yet an additional display of the foregoing parameters.

An embodiment may also include the monitor **1000** advantageously defining regions of wellness/severity of the monitored patient. For example, because the graph **1172** comprises two dimensions, the monitor **1000** may advantageously define regions where the patient's measured physiological parameters are considered acceptable, regions where the patient is considered at risk, regions where the patient is critical, and the like. For example, one region of acceptability may include a high SpO_2 and a low 1-$SpaO_2$, another region of risk may include a high SpO_2 and a high 1-$SpaO_2$, and another critical region may include a low SpO_2 and a high 1-$SpaO_2$. Moreover, an artisan will recognize from the dis-

closure herein that different parameters may also be combined to provide readily identifiable indications of patient wellness.

In addition to or as an alternative to the two dimensional $SpaO_2$ graph **1172**, the monitor **1000** may also include a three dimensional graph, such as, for example, extending the graph **1172** along the variable of time. In this embodiment, the forgoing regions advantageously become three dimensional surfaces of wellness. Moreover, trend data may also be advantageously added to the surface to provide a history of when particular monitored parameters dipped in and out of various surfaces of wellness, risk, criticality, or the like. Such trend data could be color-coded, text identified, or the like. An artisan will also recognize that such surfaces may be dynamic. For example, measurements of HbCO> about 5 may dictate that trend data showing SpO_2< about 90% should be considered critical; however, measurements of HbCO< about 5 may dictate only SpO_2< about 85% would be critical. Again, an artisan will recognize from the disclosure herein other parameter combinations to create a wide variety of wellness/critical regions or surfaces that provide readily available visual or audio indications of patient well being, trigger specific alarms, or the like.

Moreover, the monitor **1000** may advantageously employ enlargement or reorganization of parameter data based on, for example, the severity of the measurement. For example, the monitor **1000** may display values for HbCO in a small portion of the screen or in the background, and when HbCO begins to approach abnormal levels, the small portion may advantageously grown as severity increases, even in some embodiments to dominate the display. Such visual alarming can be combined with audio alarms such as announcements, alarms, rising frequencies, or the like, and other visual alarms such as flashing, coloration, or the like to assist a caregiver in noticing the increasing severity of a monitored parameter. In an embodiment, a location of the display of an alarming value is changed to be displayed in a larger display area, such as **1102**, so as to be readily noticeable and its display values readily ascertainable.

Although the foregoing invention has been described in terms of certain preferred embodiments, other embodiments will be apparent to those of ordinary skill in the art from the disclosure herein. For example, the monitor **100** may advantageously be adapted to monitor or be included in a monitor capable of measuring physiological parameters other than those determined through absorption spectroscopy, such as, for example, blood pressure, ECG, EKG, respiratory rates, volumes, inputs for blood pressure sensors, acoustical sensors, and the like. Moreover, the monitor **100** may be adapted for wireless communication to and from the sensor **106**, and/or to and from other monitoring devices, such as, for example, multi-parameter or legacy monitoring devices.

Also, other combinations, omissions, substitutions and modifications will be apparent to the skilled artisan in view of the disclosure herein. Accordingly, the present invention is not intended to be limited by the reaction of the preferred embodiments, but is to be defined by reference to the appended claims.

Additionally, all publications, patents, and patent applications mentioned in this specification are herein incorporated by reference to the same extent as if each individual publication, patent, or patent application was specifically and individually indicated to be incorporated by reference.

What is claimed is:

1. A patient monitor capable of measuring at least two physiological parameters, the patient monitor comprising a display capable of displaying a measured value of a first physiological parameter of body tissue of a monitored patient in a first display area or displaying a measured value of a second physiological parameter of the body tissue in a second display area where the first display area and the second display area comprise at least some common display area capable of displaying information, wherein the common display area changes from displaying one of the measured values of the first or second physiological parameter to displaying the other of the measured values based on an occurrence of an event, the event being the measured value of one of the first or second physiological parameters approaching one or more threshold values indicative of a worsening state of a patient.

2. The patient monitor of claim **1**, wherein the first display area and the second display area comprise the common display area.

3. The patient monitor of claim **1**, wherein activation of a user input causes the common display area to change from displaying one of the measured value of the first or second physiological parameter to displaying the other of the measured value of the first or second physiological parameter.

4. The patient monitor of claim **1**, wherein the common display area is configured to default to displaying one of the measured values of the first or second physiological parameters.

5. The patient monitor of claim **1**, wherein the measured value of the first physiological parameter comprises an invasively measured value.

6. The patient monitor of claim **1**, wherein the measured value of the first physiological parameter comprises a non-invasively measured value.

7. The patient monitor of claim **1**, wherein the measured value of the first physiological parameter comprises glucose.

8. The patient monitor of claim **1**, wherein the measured value of the first physiological parameter comprises an indication of oxygen saturation and the measured value of the second physiological parameter comprises an indication of carbon monoxide saturation.

9. The patient monitor of claim **1**, wherein the measured value of the first physiological parameter comprises an indication of oxygen saturation and the measured value of the second physiological parameter comprises an indication of methemoglobin saturation.

10. The patient monitor of claim **1**, wherein the measured value of the first physiological parameter comprises an indication of carbon monoxide saturation and the measured value of the second physiological parameter comprises an indication of methemoglobin saturation.

11. The patient monitor of claim **1**, wherein an aspect of the display changes to illustrate a change in the severity of one of the measured values of the first or second physiological parameters.

12. The patient monitor of claim **11**, wherein the aspect that changes comprises a display color.

13. The patient monitor of claim **11**, wherein the aspect that changes comprises a display size.

14. The patient monitor of claim **11**, wherein the aspect that changes comprises a display intensity.

15. A patient monitor capable of measuring at least two physiological parameters, the patient monitor comprising a display capable of displaying a measured value of a first physiological parameter of body tissue of a monitored patient in a first display area or displaying a measured value of a second physiological parameter of the body tissue in a second display area where the first display area and the second display area comprise at least some common display area capable of displaying information, wherein the common display area changes from displaying one of the measured values

of the first or second physiological parameters to displaying the other of the measured values of the first or second physiological parameters based on an occurrence of an event, the event being one of the measured values of the first or second physiological parameters alarming.

16. The patient monitor of claim **15**, wherein an aspect of an alarm changes when the common display area changes from displaying one of the measured values of the first or second physiological parameters.

17. The patient monitor of claim **16**, wherein the aspect that changes comprises a display color.

18. A patient monitor capable of measuring at least two physiological parameters, the patient monitor comprising a display capable of displaying a measured value of a first physiological parameter of body tissue of a monitored patient in a first display area or displaying a measured value of a second physiological parameter of the body tissue in a second display area where the first display area and the second display area comprise at least some common display area capable of displaying information, wherein the common display area changes from displaying one of the measured values of the first or second physiological parameters to displaying the other of the measured values of the first or second physiological parameters automatically based on which is a more critical one of the measured values of the first or second physiological parameters.

19. The patient monitor of claim **18**, wherein measured values of the first and second physiological parameters are determined using an output signal of a light sensitive detector capable of detecting light attenuated by the body tissue.

20. The patient monitor of claim **18**, wherein at least one of measured physiological parameters is determined noninvasively.

21. A method of displaying two physiological parameter measurements using a display location of a display of a patient monitoring device, the display location being generally capable of displaying a single physiological parameter measurement, the method comprising:

displaying a measured value of a first physiological parameter in a display location of an electronic display; and

replacing the display of the measured value of the first physiological parameter with a display of a measured value of a second physiological parameter in the display location when a change in the measurement of the second physiological parameter indicates a worsening state of the patient.

22. The method of claim **21**, wherein the indication of the worsening state comprises an alarm condition.

23. The method of claim **21**, wherein the measured value of the first physiological parameter comprises an invasively measured value.

24. The method of claim **21**, wherein the measured value of the first physiological parameter comprises an indication of oxygen saturation and the measured value of the second physiological parameter comprises an indication of carbon monoxide saturation.

25. The method of claim **21**, wherein the measured value of the first physiological parameter comprises an indication of oxygen saturation and the measured value of the second physiological parameter comprises an indication of methemoglobin saturation.

26. The method of claim **21**, wherein the measured value of the first physiological parameter comprises an indication of carbon monoxide saturation and the measured value of the second physiological parameter comprises an indication of methemoglobin saturation.

27. A patient monitor capable of determining a plurality of physiological parameters from an output signal of a light sensitive detector capable of detecting light attenuated by body tissue, the patient monitor comprising:

a display capable of displaying a measured value of a first blood parameter of body tissue of a monitored patient or displaying a measured value of a second blood parameter of the body tissue; and

a user input button, the activation of which causes the display to change from displaying the measured value of the first blood parameter to displaying the measured value of the second blood parameter, wherein the display also changes from displaying the measured value of the first blood parameter to displaying the measured value of the second blood parameter when the second blood parameter passes an alarm threshold,

wherein the measured values of the first and second blood parameters are determined using an output signal of a noninvasive light sensitive detector capable of detecting light attenuated by the body tissue.

28. The patient monitor of claim **27**, wherein the display shifts a positioning of the display of the second blood parameter with respect to a positioning of the display of the first blood parameter.

29. The patient monitor of claim **27**, wherein the change is for a predetermined duration and after expiration of the predetermined duration, the display changes back to displaying the measured value of the first blood parameter.

30. The patient monitor of claim **27**, wherein the display of the measured value of the first blood parameter comprises a first color under normal conditions and the display of the measured value of the second blood parameter comprises a second color under normal conditions.

31. The patient monitor of claim **27**, further comprising a sensor indicator capable of indicating whether an attached sensor can provide sufficient data to determine the measured value of the second blood parameter.

32. The patient monitor of claim **27**, wherein the attached sensor can provide data through the output signal and through a memory device.

33. The patient monitor of claim **27**, wherein the display displays the first blood parameter when the attached sensor cannot provide the sufficient data.

34. The patient monitor of claim **27**, further comprising a memory for storing trend data on one or more of the first and second blood parameters.

35. The patient monitor of claim **27**, further comprising an indicator capable of indicating the signal quality of the signals used to determine at least one of the measured values of the first and second blood parameters.

36. The patient monitor of claim **27**, further comprising an alarm corresponding to either of the measured values of the first and second blood parameters falling below predetermined associated threshold values.

37. The patient monitor of claim **36**, wherein the alarm comprises at least one of an audio or visual alarm.

38. The patient monitor of claim **27**, further comprising an additional display indicating perfusion through the body tissue.

39. The patient monitor of claim **27**, wherein the first blood parameter comprises a percent oxygen saturation and the second blood parameter comprises a percent carbon monoxide saturation.

40. The patient monitor of claim **39**, comprising an additional display capable of indicating the percent carbon monoxide saturation.

41. The patient monitor of claim **39**, comprising an additional display capable of indicating the percent methemoglobin saturation.

42. The patient monitor of claim **27**, wherein the display comprises a first display and the patient monitor further comprises a second display capable of displaying a pulse rate.

43. The patient monitor of claim **42**, wherein the second display is capable of displaying the pulse rate when the first display displays the measured value of the first blood parameter.

44. The patient monitor of claim **42**, wherein the second display is capable of displaying indicia identifying the second blood parameter when the first display displays the measured value of the second blood parameter.

45. The patient monitor of claim **27**, wherein a first activation type of the user input button causes the change to be for a predetermined duration and wherein a second activation type causes the change to be for an undetermined duration.

46. The patient monitor of claim **45**, wherein the first activation type comprises a first depression of the user input button and the second activation type comprises an additional depression of the user input button.

47. The patient monitor of claim **45**, wherein the first activation type comprises a short duration first depression of the user input button and the second activation type comprises a long duration first depression of the user input button.

* * * * *

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO. : 8,190,223 B2
APPLICATION NO. : 11/367033
DATED : May 29, 2012
INVENTOR(S) : Ammar Al-Ali et al.

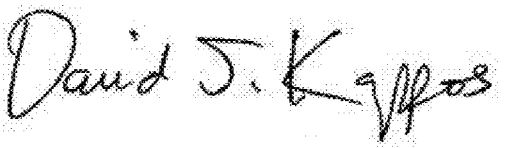
It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

On Title Page 2 (Item 56), Column 1, Line 15 (Approx.), Under U.S. Patent Documents, below "Martin" insert --4,854,328 |08-1989 |Pollack--.

On Title Page 4 (Item 56), Column 1, Line 75, Under U.S. Patent Documents, change "Chin et al." to --O'Neil et al.--.

In Column 18, Line 54, change "11" to --11**H**--.

Signed and Sealed this
Thirteenth Day of November, 2012



David J. Kappos
Director of the United States Patent and Trademark Office

US008190223C1

(12) EX PARTE REEXAMINATION CERTIFICATE (9610th)

United States Patent
Al-Ali et al.

(10) **Number: US 8,190,223 C1**
(45) **Certificate Issued: Apr. 24, 2013**

(54) **NONINVASIVE MULTI-PARAMETER PATIENT MONITOR**

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(73) Assignee: **Cercacor Laboratories, Inc.**, Irvine, CA (US)

Reexamination Request:
No. 90/012,559, Sep. 13, 2012

Reexamination Certificate for:

Patent No.:	**8,190,223**
Issued:	**May 29, 2012**
Appl. No.:	**11/367,033**
Filed:	**Mar. 1, 2006**

Certificate of Correction issued Nov. 13, 2012

Related U.S. Application Data

(60) Provisional application No. 60/657,596, filed on Mar. 1, 2005, provisional application No. 60/657,281, filed on Mar. 1, 2005, provisional application No. 60/657,268, filed on Mar. 1, 2005, provisional application No. 60/657,759, filed on Mar. 1, 2005.

(51) **Int. Cl.**
A61B 5/00 (2006.01)

(52) **U.S. Cl.**
USPC **600/300**; 600/323; 600/324

(58) **Field of Classification Search** ..... None
See application file for complete search history.

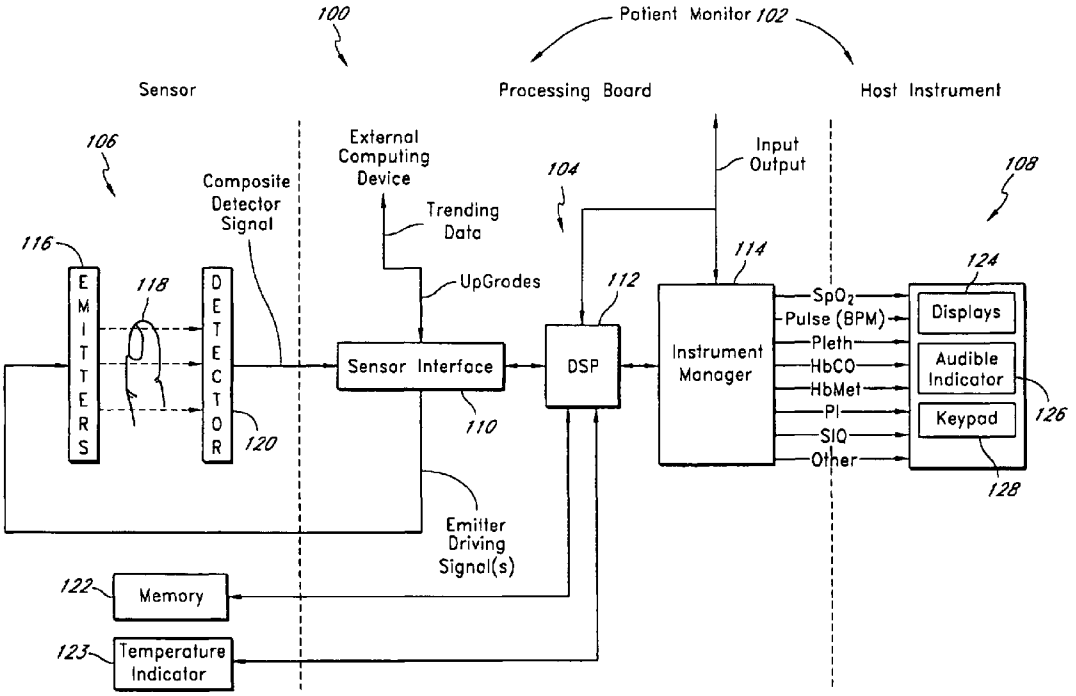
(56) **References Cited**

To view the complete listing of prior art documents cited during the proceeding for Reexamination Control Number 90/012,559, please refer to the USPTO's public Patent Application Information Retrieval (PAIR) system under the Display References tab.

Primary Examiner — Robert Nasser

(57) **ABSTRACT**

Embodiments of the present disclosure include a handheld multi-parameter patient monitor capable of determining multiple physiological parameters from the output of a light sensitive detector capable of detecting light attenuated by body tissue. For example, in an embodiment, the monitor is capable of advantageously and accurately displaying one or more of pulse rate, plethysmograph data, perfusion quality, signal confidence, and values of blood constituents in body tissue, including for example, arterial carbon monoxide saturation ("HbCO"), methemoglobin saturation ("HbMet"), total hemoglobin ("Hbt"), arterial oxygen saturation ("SpO_2"), fractional arterial oxygen saturation ("$SpaO_2$"), or the like. In an embodiment, the monitor advantageously includes a plurality of display modes enabling more parameter data to be displayed than the available physical display real estate.



EX PARTE REEXAMINATION CERTIFICATE ISSUED UNDER 35 U.S.C. 307

THE PATENT IS HEREBY AMENDED AS INDICATED BELOW.

Matter enclosed in heavy brackets [ ] appeared in the patent, but has been deleted and is no longer a part of the patent; matter printed in italics indicates additions made to the patent.

AS A RESULT OF REEXAMINATION, IT HAS BEEN DETERMINED THAT:

The patentability of claims **21-26** is confirmed.

Claims **1**, **3**, **7**, **13**, **15**, **18**, **27-28** and **45** are determined to be patentable as amended.

Claims **2**, **4-6**, **8-12**, **14**, **16-17**, **19-20**, **29-44** and **46-47**, dependent on an amended claim, are determined to be patentable.

1. A patient monitor capable of measuring at least two physiological parameters, the patient monitor comprising a display capable of displaying a measured value of a first physiological parameter of body tissue of a monitored patient in a first display area or displaying a measured value of a second physiological parameter of the body tissue in a second display area where the first display area and the second display area comprise at least some common display area capable of displaying information, wherein *in* the common display area **[**changes from displaying**]** *, the display of* one of the measured values of the first or second physiological parameter **[**to displaying**]** *is replaced with* the other of the measured values based on an occurrence of an event, the event being the measured value of one of the first or second physiological parameters approaching one or more threshold values indicative of a worsening state of a patient.

3. The patient monitor of claim **1**, wherein activation of a user input causes the common display area to **[**change from displaying**]** *replace* one of the measured value of the first or second physiological parameter **[**to displaying**]** *with* the other of the measured value of the first or second physiological parameter.

7. **[**The patient monitor of claim **1]** *A patient monitor capable of measuring at least two physiological parameters, the patient monitor comprising a display capable of displaying a measured value of a first physiological parameter of body tissue of a monitored patient in a first display area or displaying a measured value of a second physiological parameter of the body tissue in a second display area where the first display area and the second display area comprise at least some common display area capable of displaying information, wherein the common display area changes from displaying one of the measured values of the first or second physiological parameter to displaying the other of the measured values based on an occurrence of an event, the event being the measured value of one of the first or second physiological parameters approaching one or more threshold values indicative of a worsening state of a patient*, wherein the measured value of the first physiological parameter comprises glucose.

13. **[**The patient monitor of claim 11**]** *A patient monitor capable of measuring at least two physiological parameters, the patient monitor comprising a display capable of displaying a measured value of a first physiological parameter of body tissue of a monitored patient in a first display area or displaying a measured value of a second physiological parameter of the body tissue in a second display area where the first display area and the second display area comprise at least some common display area capable of displaying information, wherein the common display area changes from displaying one of the measured values of the first or second physiological parameter to displaying the other of the measured values based on an occurrence of an event, the event being the measured value of one of the first or second physiological parameters approaching one or more threshold values indicative of a worsening state of a patient, wherein an aspect of the display changes to illustrate a change in the severity of one of the measured values of the first or second physiological parameters*, wherein the aspect that changes comprises a display size.

15. A patient monitor capable of measuring at least two physiological parameters, the patient monitor comprising a display capable of displaying a measured value of a first physiological parameter of body tissue of a monitored patient in a first display area or displaying a measured value of a second physiological parameter of the body tissue in a second display area where the first display area and the second display area comprise at least some common display area capable of displaying information, wherein *in* the common display area **[**changes from displaying**]** *, the display of* one of the measured values of the first or second physiological parameters **[**to displaying**]** *is replaced with* the other of the measured values of the first or second physiological parameters based on an occurrence of an event, the event being one of the measured values of the first or second physiological parameters alarming.

18. A patient monitor capable of measuring at least two physiological parameters, the patient monitor comprising a display capable of displaying a measured value of a first physiological parameter of body tissue of a monitored patient in a first display area or displaying a measured value of a second physiological parameter of the body tissue in a second display area where the first display area and the second display area comprise at least some common display area capable of displaying information, wherein *in* the common display area **[**changes from displaying**]** *, the display of* one of the measured values of the first or second physiological parameters **[**to displaying**]** *is replaced with* the other of the measured values of the first or second physiological parameters automatically based on which is a more critical one of the measured values of the first or second physiological parameters.

27. A patient monitor capable of determining a plurality of physiological parameters from an output signal of a light sensitive detector capable of detecting light attenuated by body tissue, the patient monitor comprising:

a display capable of displaying a measured value of a first blood parameter of body tissue of a monitored patient or displaying a measured value of a second blood parameter of the body tissue; and

a user input button, the activation of which **[**causes**]** *replaces* the display **[**to change from displaying**]** *of* the measured value of the first blood parameter **[**to displaying**]** *with* the measured value of the second blood parameter, wherein the display **[**also changes from displaying**]** *of* the measured value of the first blood parameter **[**to displaying**]** *is replaced by* the measured value of the second blood parameter when the second blood parameter passes an alarm threshold,

wherein the measured values of the first and second blood parameters are determined using an output signal of a

noninvasive light sensitive detector capable of detecting light attenuated by the body tissue.

28. **[**The patient monitor of claim **27]** *A patient monitor capable of determining a plurality of physiological parameters from an output signal of a light sensitive detector capable of detecting light attenuated by body tissue, the patient monitor comprising:*

a display capable of displaying a measured value of a first blood parameter of body tissue of a monitored patient or displaying a measured value of a second blood parameter of the body tissue; and

a user input button, the activation of which causes the display to change from displaying the measured value of the first blood parameter to displaying the measured value of the second blood parameter, wherein the display also changes from displaying the measured value of the first blood parameter to displaying the measured value of the second blood parameter when the second blood parameter passes an alarm threshold,

wherein the measured values of the first and second blood parameters are determined using an output signal of a noninvasive light sensitive detector capable of detecting light attenuated by the body tissue,

wherein the display shifts a positioning of the display of the second blood parameter with respect to a positioning of the display of the first blood parameter.

45. **[**The patient monitor of claim **27]** *A patient monitor capable of determining a plurality of physiological parameters from an output signal of a light sensitive detector capable of detecting light attenuated by body tissue, the patient monitor comprising:*

a display capable of displaying a measured value of a first blood parameter of body tissue of a monitored patient or displaying a measured value of a second blood parameter of the body tissue; and

a user input button, the activation of which causes the display to change from displaying the measured value of the first blood parameter to displaying the measured value of the second blood parameter, wherein the display also changes from displaying the measured value of the first blood parameter to displaying the measured value of the second blood parameter when the second blood parameter passes an alarm threshold,

wherein the measured values of the first and second blood parameters are determined using an output signal of a noninvasive light sensitive detector capable of detecting light attenuated by the body tissue,

wherein a first activation type of the user input button causes the change to be for a predetermined duration and wherein a second activation type causes the change to be for an undetermined duration.

* * * * *

US010984911B2

(12) **United States Patent**
Smith et al.

(10) **Patent No.: US 10,984,911 B2**
(45) **Date of Patent: Apr. 20, 2021**

(54) **MULTIPLE WAVELENGTH SENSOR EMITTERS**

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(73) Assignee: **Cercacor Laboratories, Inc.**, Irvine, CA (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: **17/028,655**

(22) Filed: **Sep. 22, 2020**

(65) **Prior Publication Data**

US 2021/0007634 A1 Jan. 14, 2021

Related U.S. Application Data

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(51) **Int. Cl.**
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(58) **Field of Classification Search**
None
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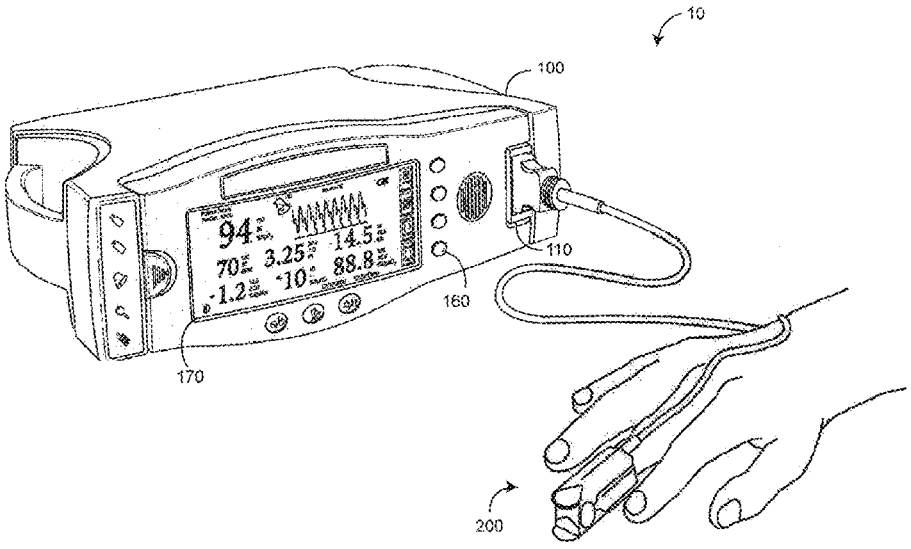
(57) **ABSTRACT**

A physiological sensor has light emitting sources, each activated by addressing at least one row and at least one column of an electrical grid. The light emitting sources are capable of transmitting light of multiple wavelengths and a detector is responsive to the transmitted light after attenuation by body tissue.

29 Claims, 48 Drawing Sheets



Related U.S. Application Data

No. 15/694,541, filed on Sep. 1, 2017, now Pat. No. 10,327,683, which is a continuation of application No. 14/472,760, filed on Aug. 29, 2014, now Pat. No. 9,750,443, which is a continuation of application No. 13/776,085, filed on Feb. 25, 2013, now Pat. No. 8,849,365, which is a continuation of application No. 12/422,915, filed on Apr. 13, 2009, now Pat. No. 8,385,996, which is a continuation of application No. 11/367,013, filed on Mar. 1, 2006, now Pat. No. 7,764,982.

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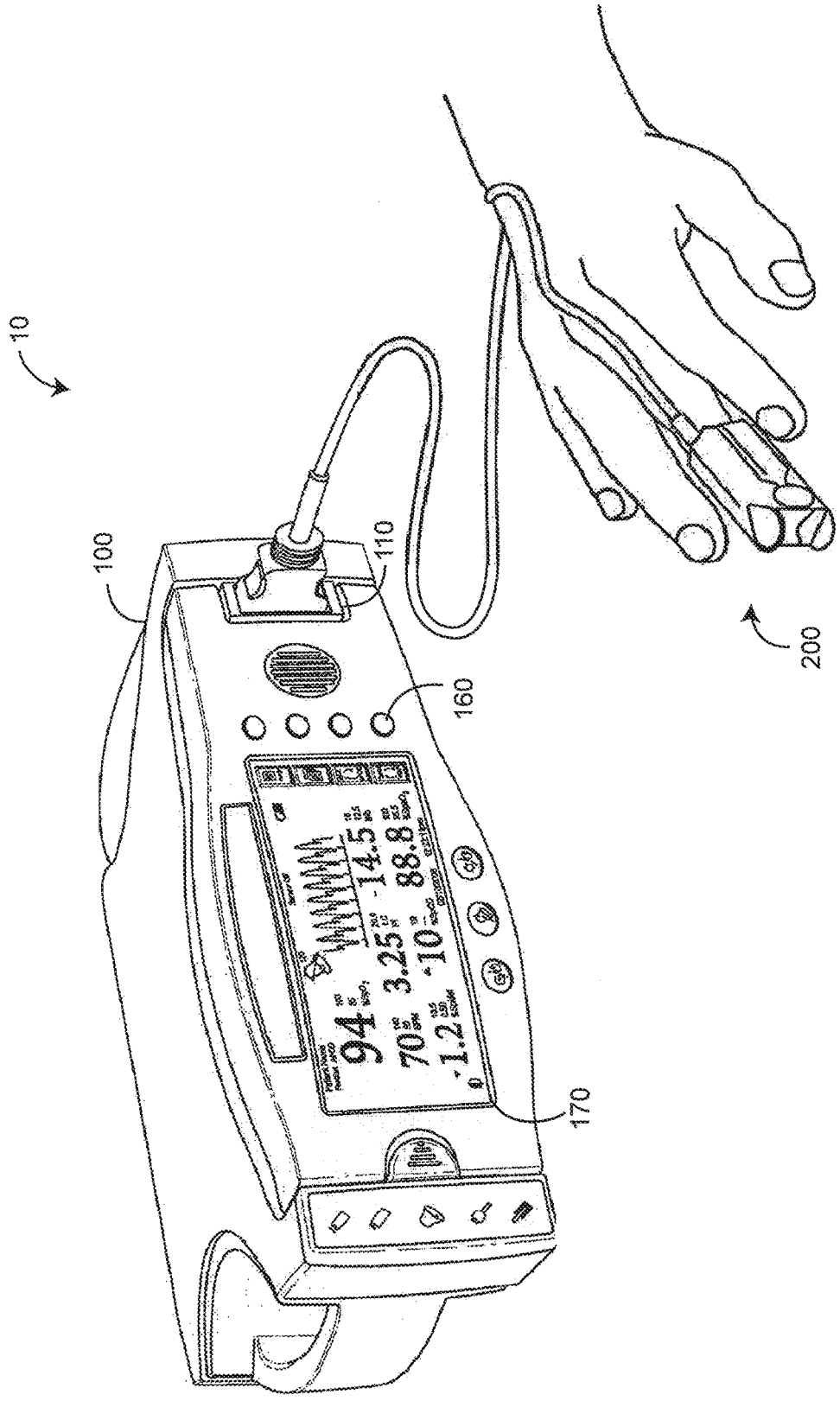


FIG. 1

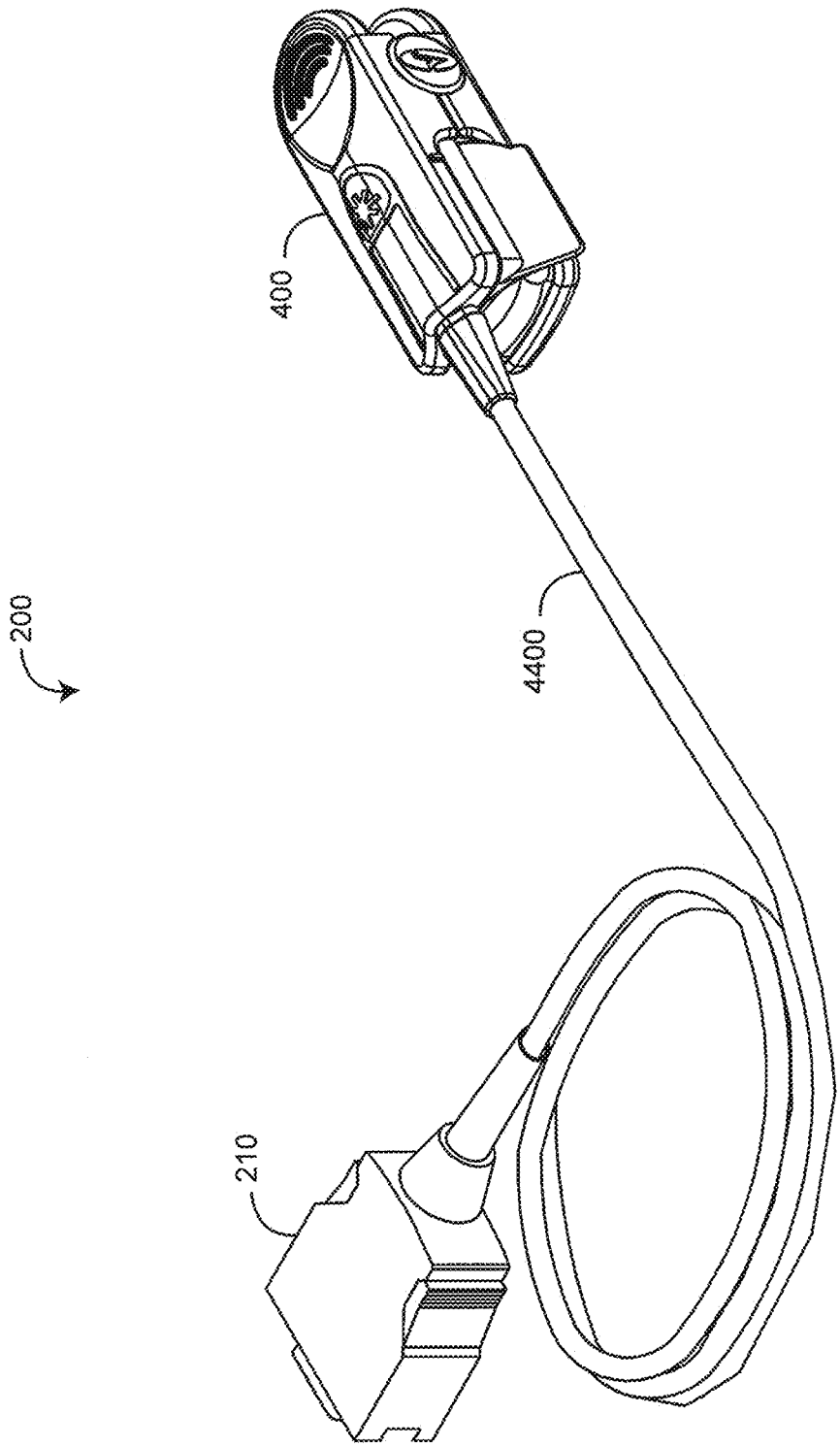


FIG. 2A

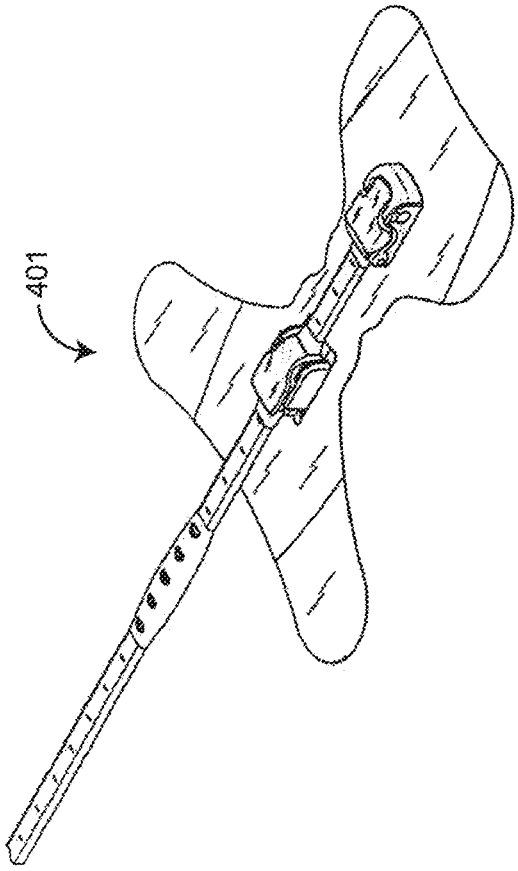


FIG. 2B

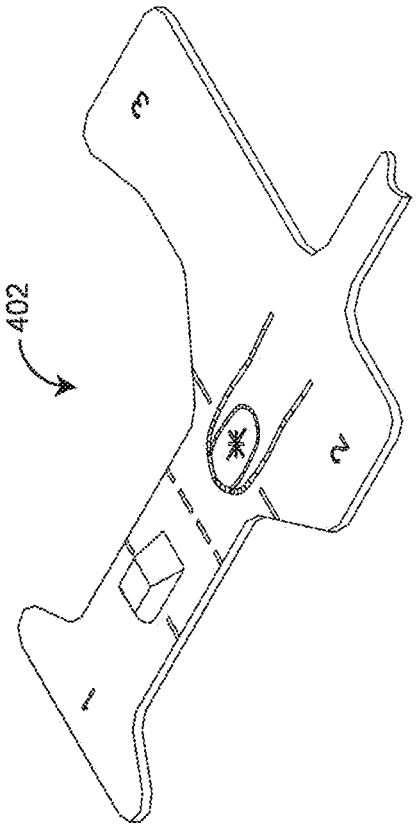


FIG. 2C

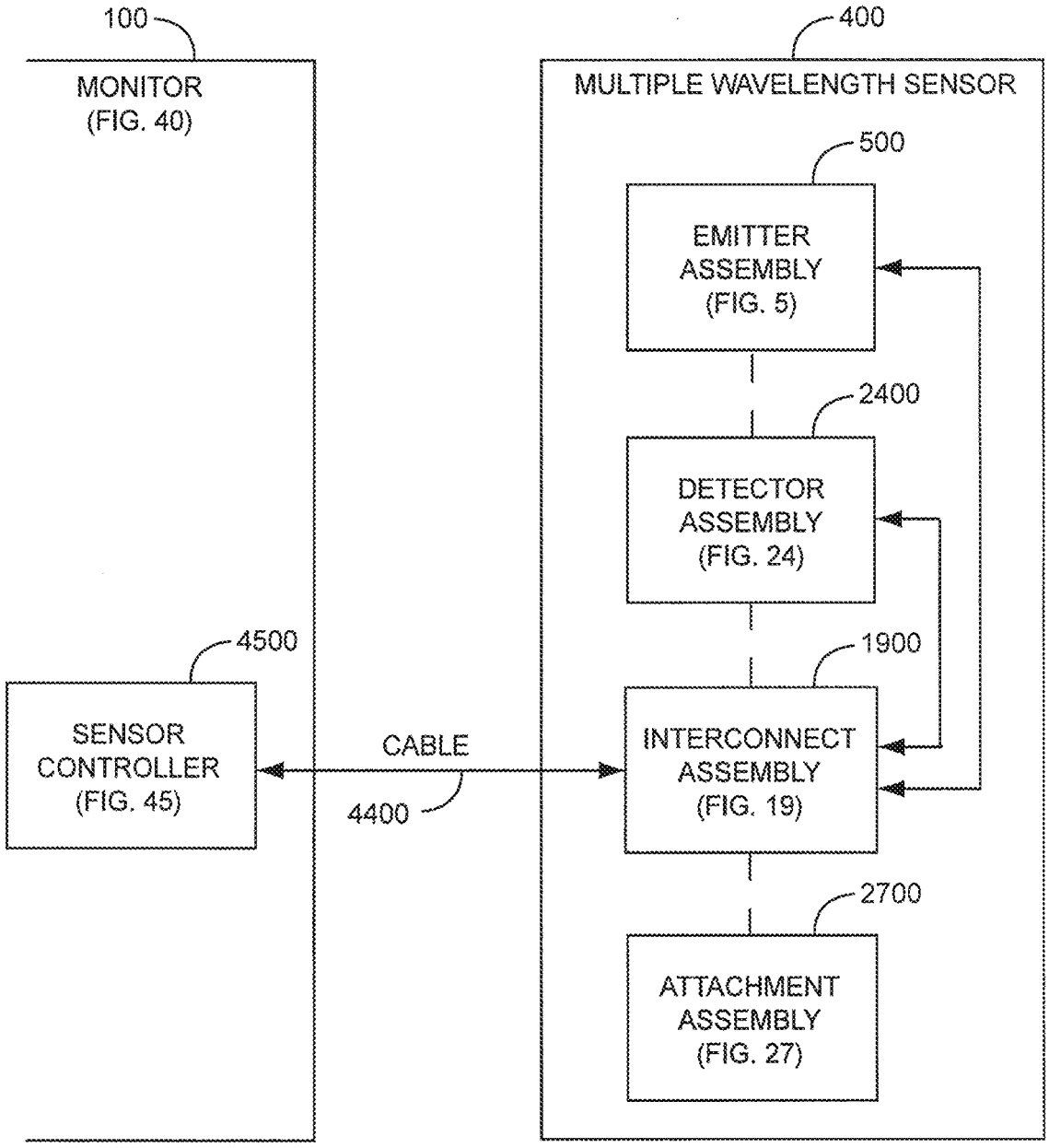

100
MONITOR
(FIG. 40)
400
MULTIPLE WAVELENGTH SENSOR
500
EMITTER ASSEMBLY
(FIG. 5)
2400
DETECTOR ASSEMBLY
(FIG. 24)
1900
INTERCONNECT ASSEMBLY
(FIG. 19)
2700
ATTACHMENT ASSEMBLY
(FIG. 27)
4500
SENSOR CONTROLLER
(FIG. 45)
CABLE
4400

FIG. 3

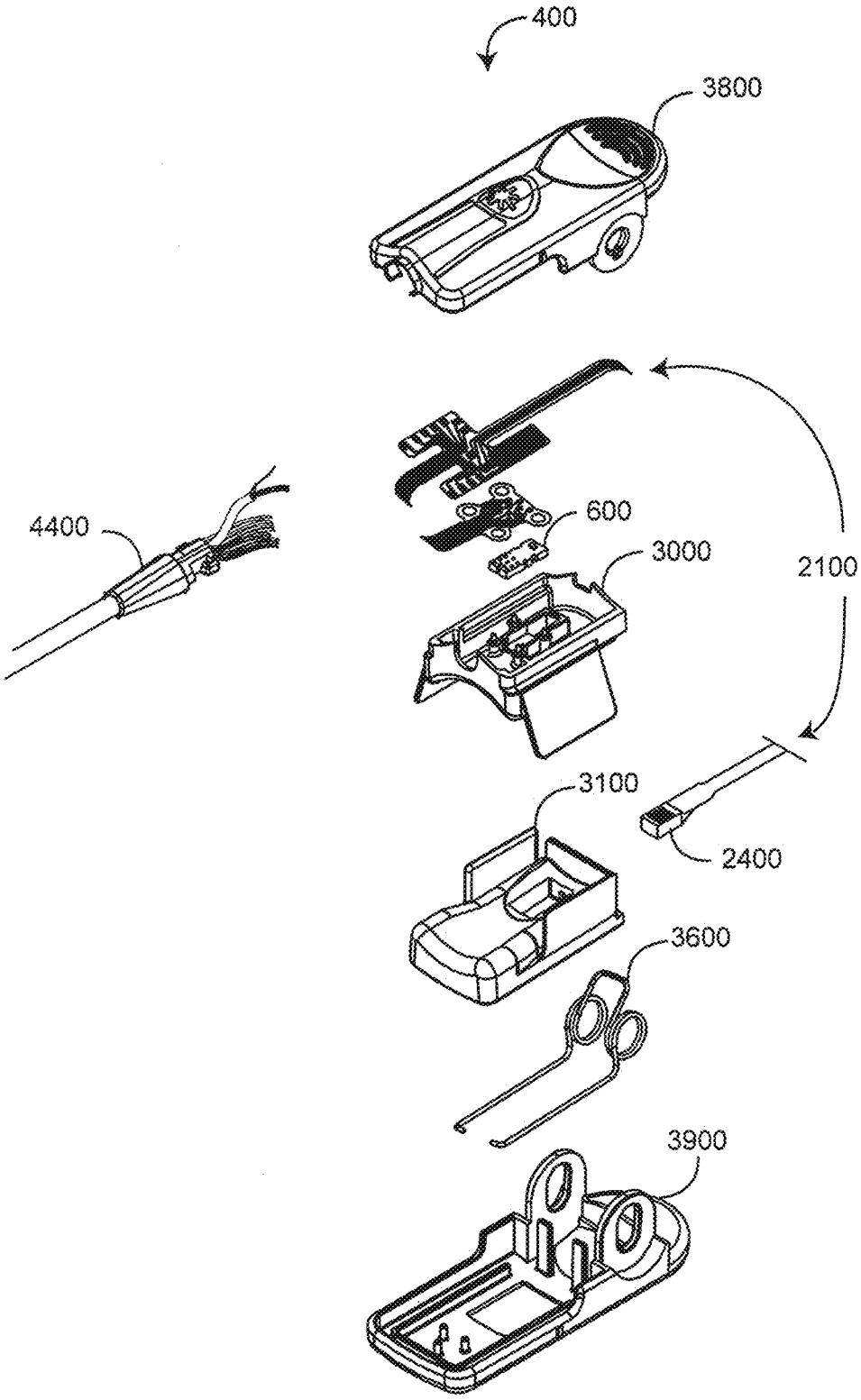


FIG. 4

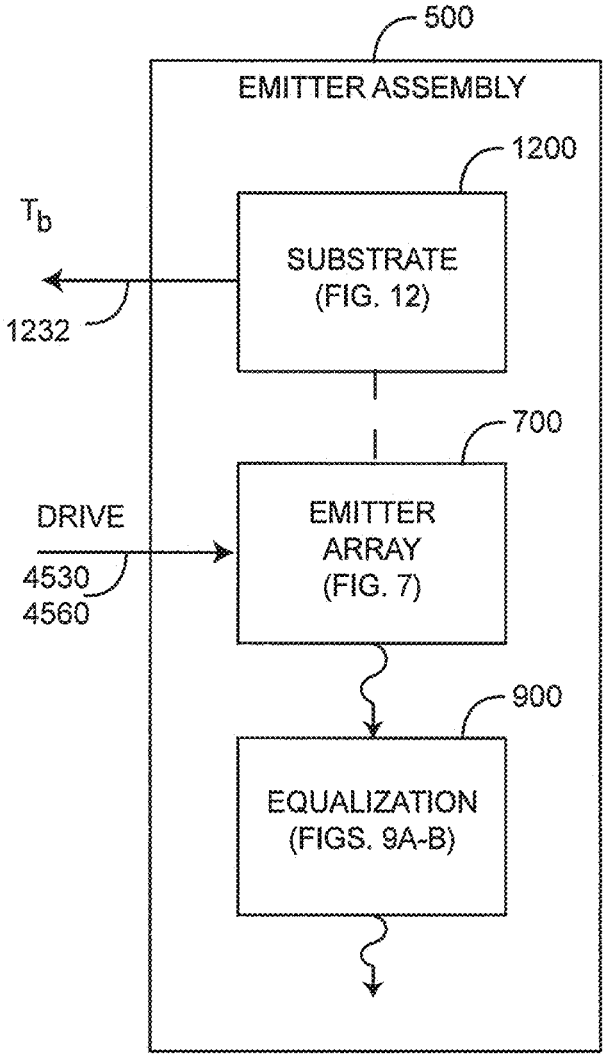

500
EMITTER ASSEMBLY
1200
T_b
SUBSTRATE
(FIG. 12)
1232
700
DRIVE
EMITTER
ARRAY
(FIG. 7)
4530
4560
900
EQUALIZATION
(FIGS. 9A-B)

FIG. 5

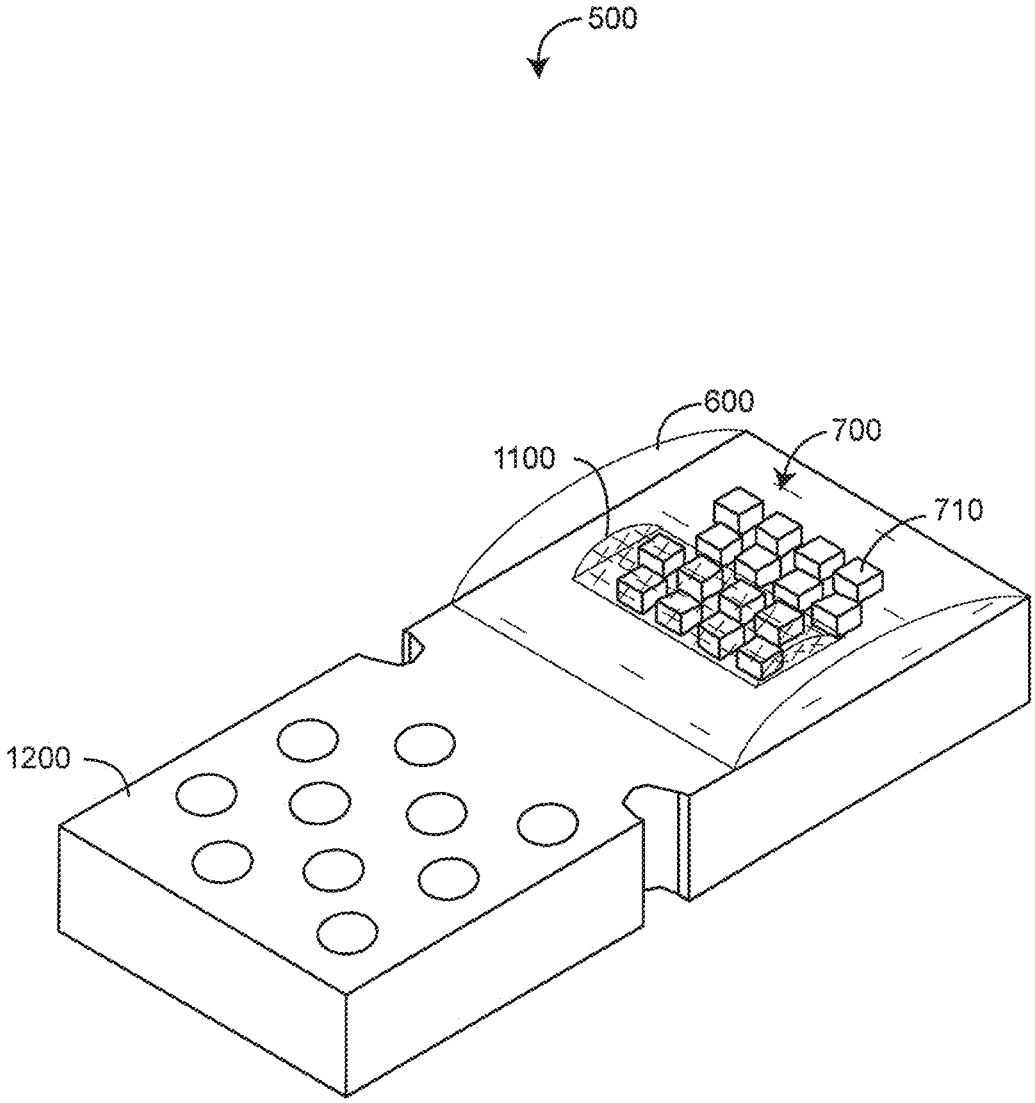


FIG. 6

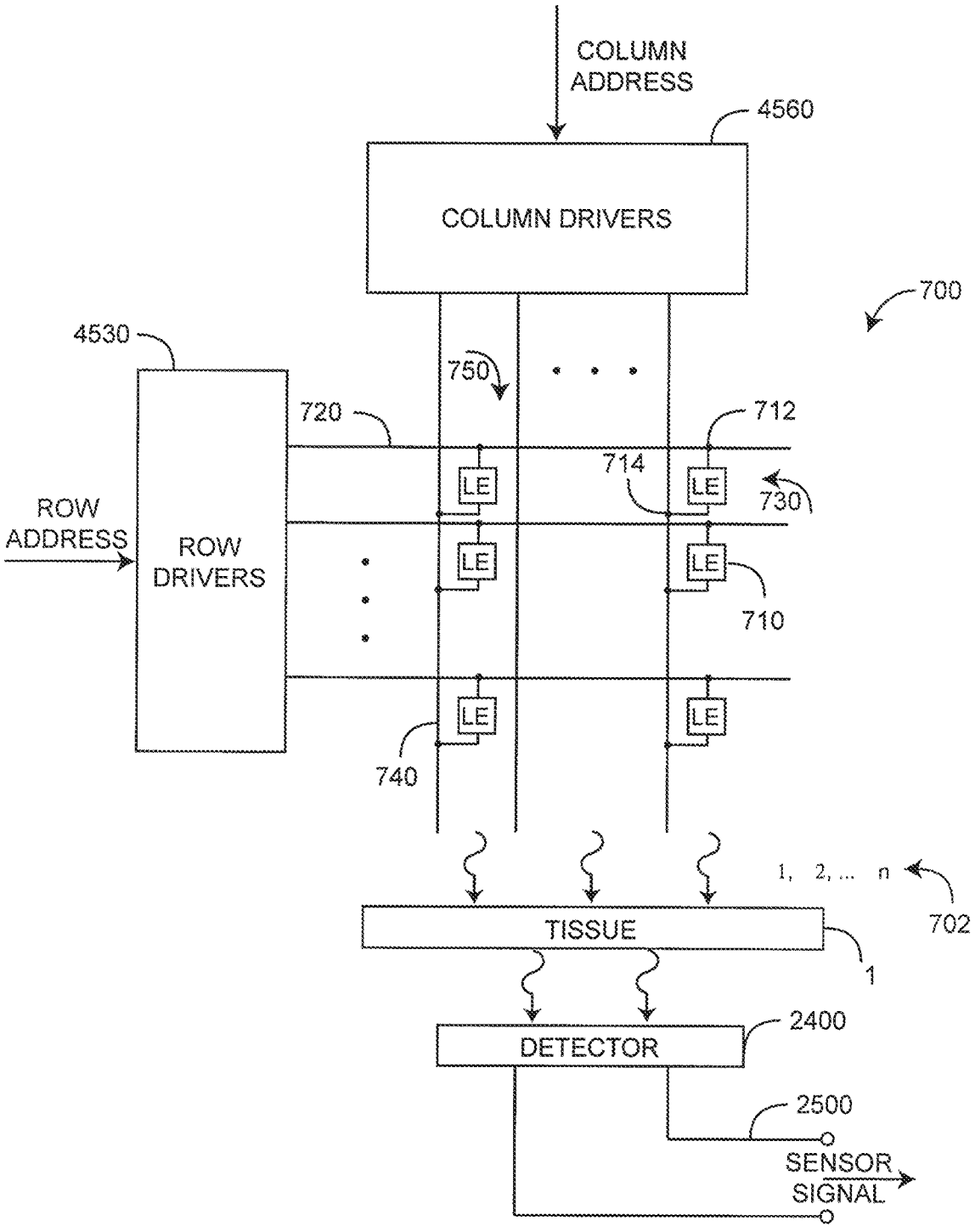

COLUMN ADDRESS
4560
COLUMN DRIVERS
700
4530
750
720
712
714
LE
730
ROW ADDRESS
ROW DRIVERS
710
740
1, 2, ... n
702
TISSUE
1
2400
DETECTOR
2500
SENSOR SIGNAL

FIG. 7

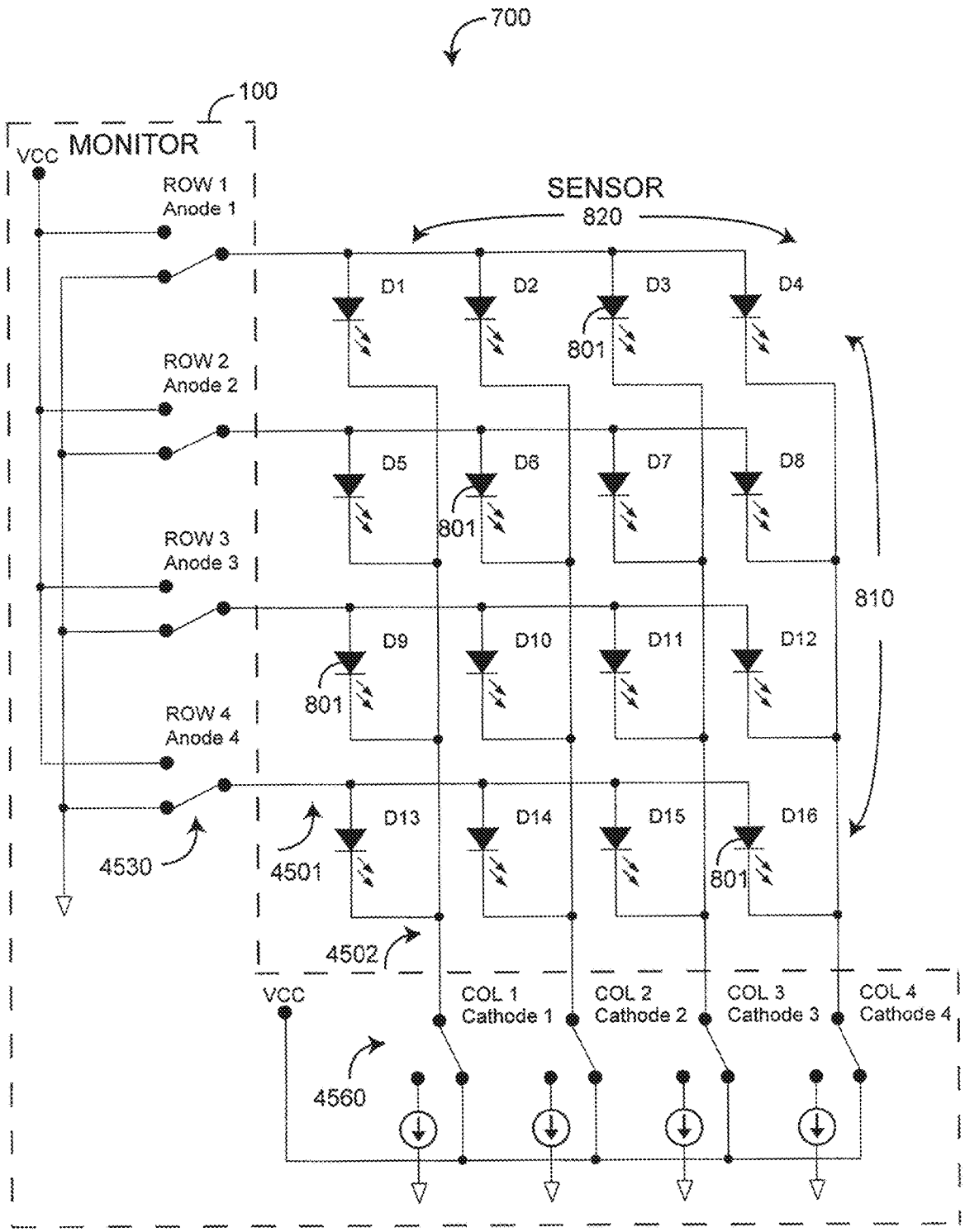

700
100
MONITOR
VCC
ROW 1
Anode 1
ROW 2
Anode 2
ROW 3
Anode 3
ROW 4
Anode 4
SENSOR
820
D1
D2
D3
D4
D5
D6
D7
D8
D9
D10
D11
D12
D13
D14
D15
D16
801
810
4530
4501
4502
4560
VCC
COL 1
Cathode 1
COL 2
Cathode 2
COL 3
Cathode 3
COL 4
Cathode 4

FIG. 8

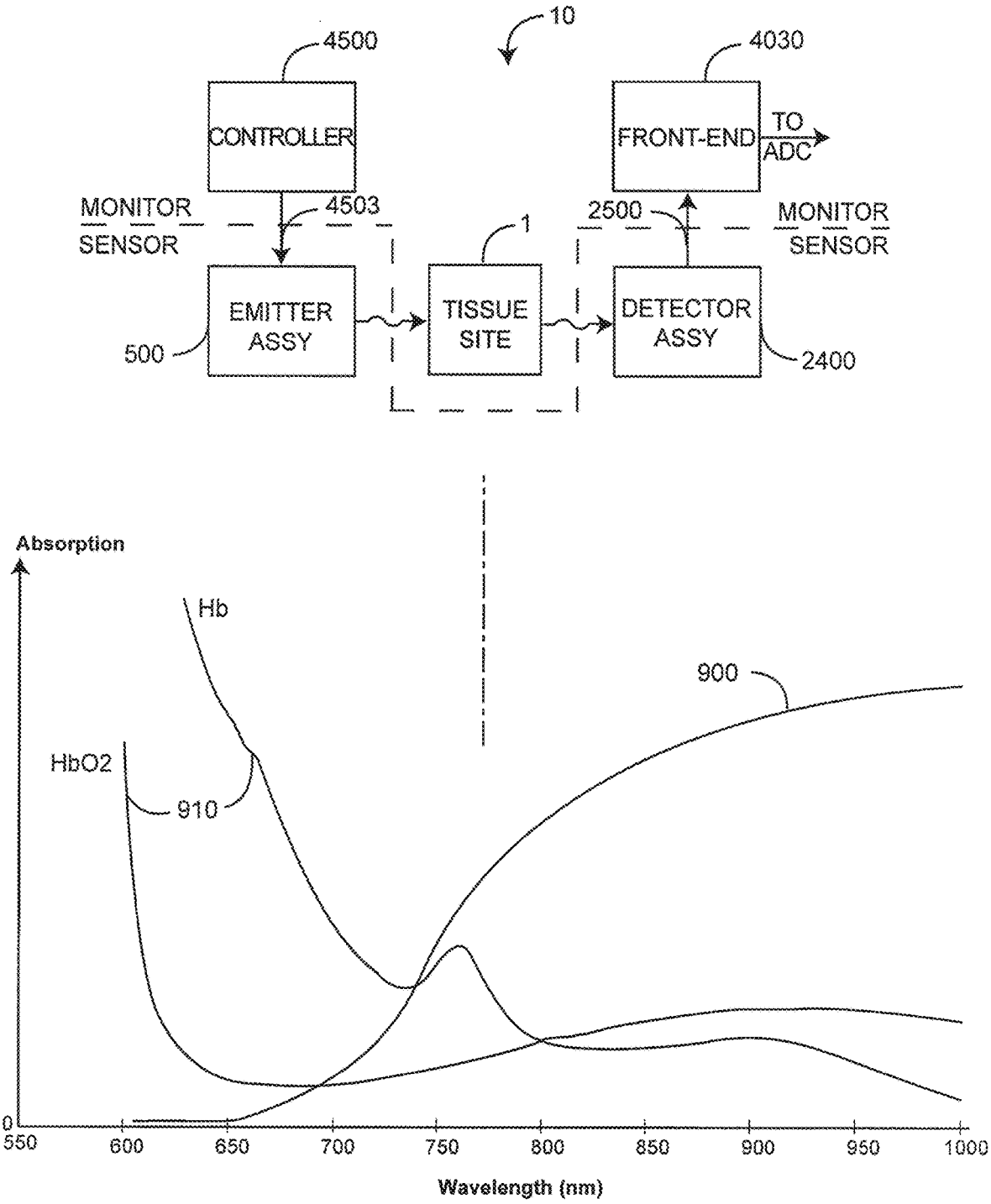

10
4500
CONTROLLER
4030
FRONT-END
TO ADC
MONITOR SENSOR
4503
2500
MONITOR SENSOR
1
EMITTER ASSY
TISSUE SITE
DETECTOR ASSY
500
2400
Absorption
Hb
900
HbO2
910
0
550
600
650
700
750
800
850
900
950
1000
Wavelength (nm)

FIG. 9

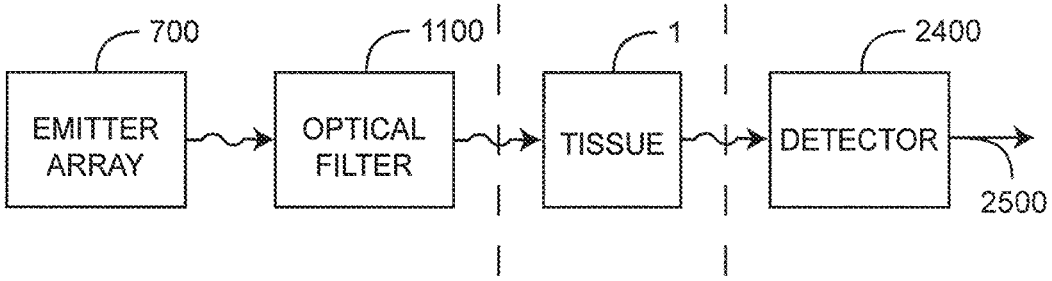


FIG. 10A

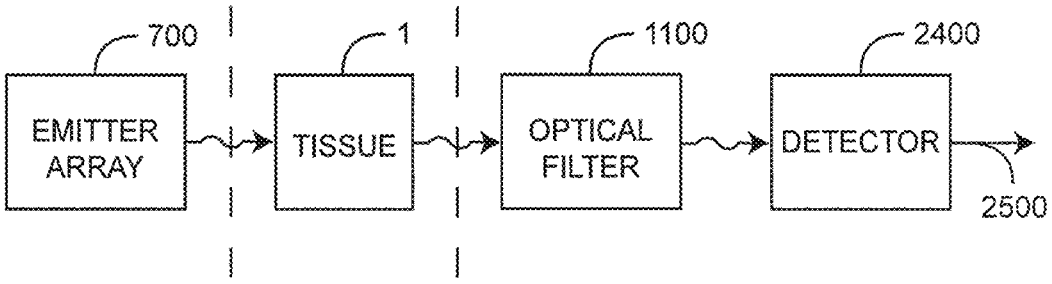


FIG. 10B

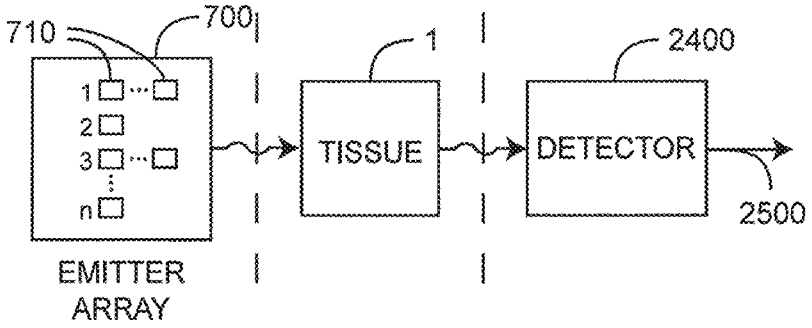


FIG. 10C

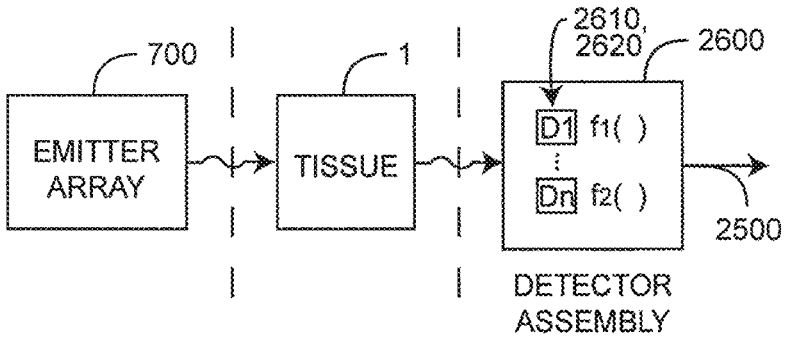


FIG. 10D

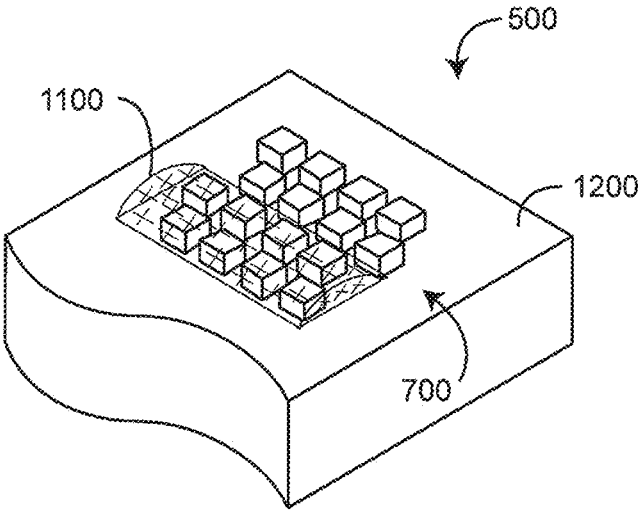


FIG. 11A

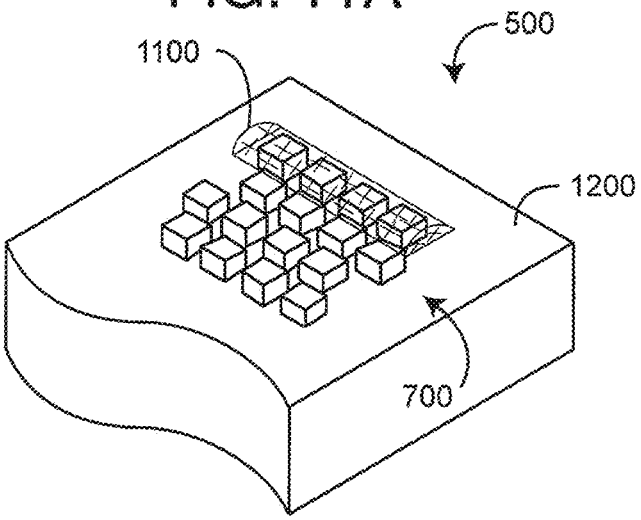


FIG. 11B

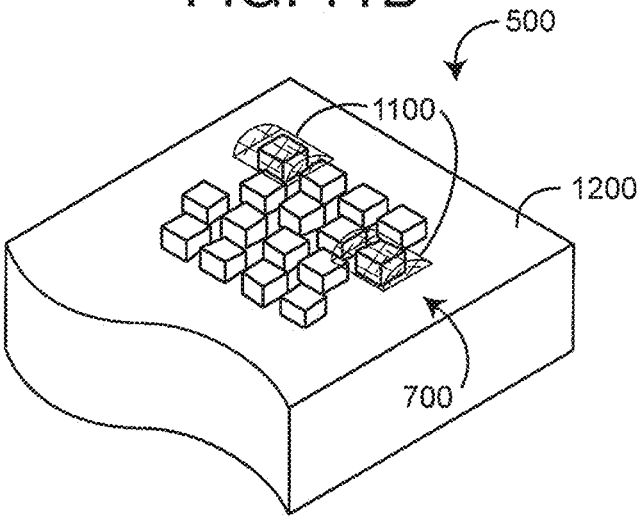


FIG. 11C

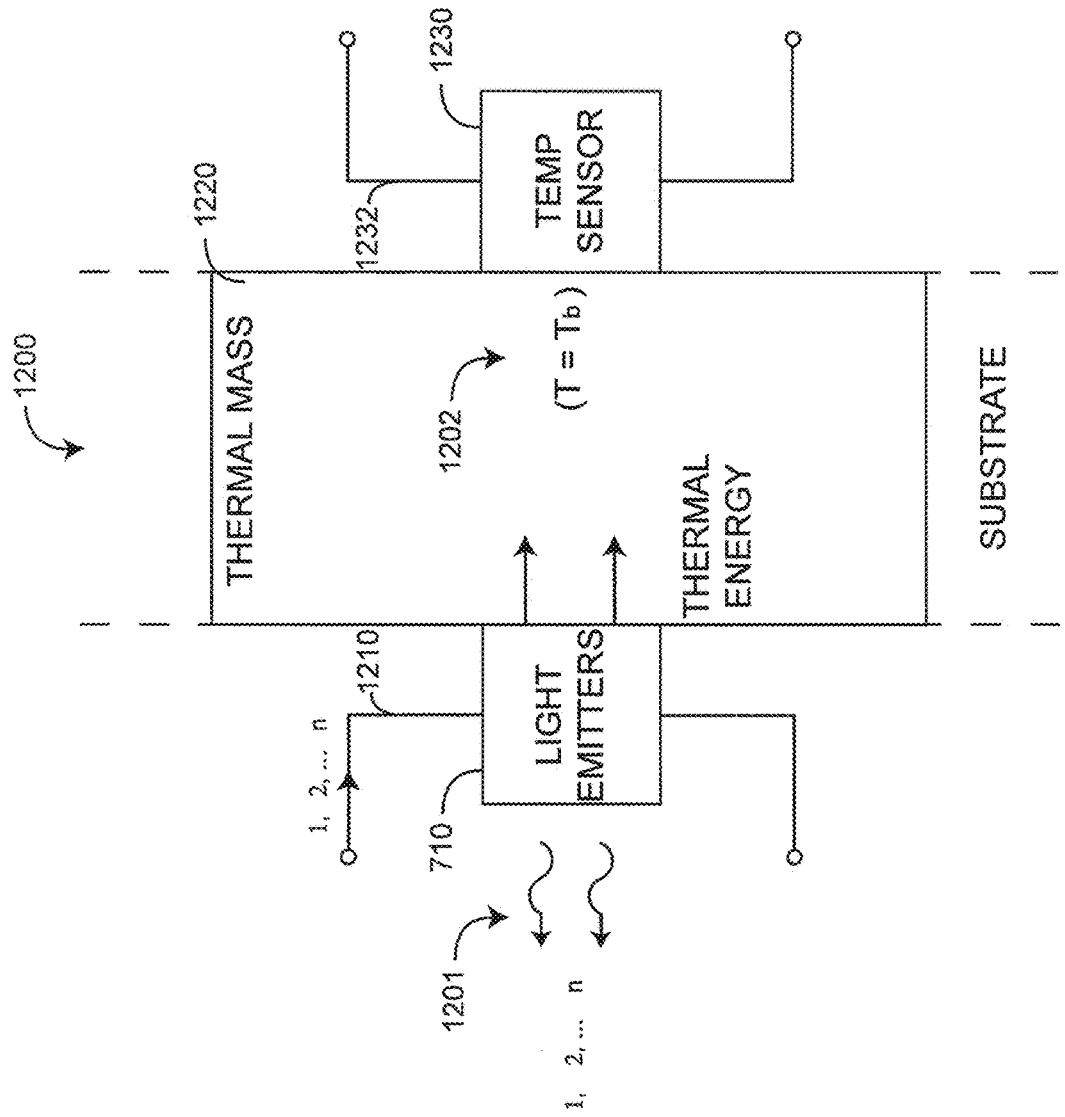

1200
THERMAL MASS
1220
1230
TEMP SENSOR
1232
1202
(T = Tb)
THERMAL ENERGY
SUBSTRATE
1210
LIGHT EMITTERS
1, 2, ... n
710
1201
1, 2, ... n

FIG. 12

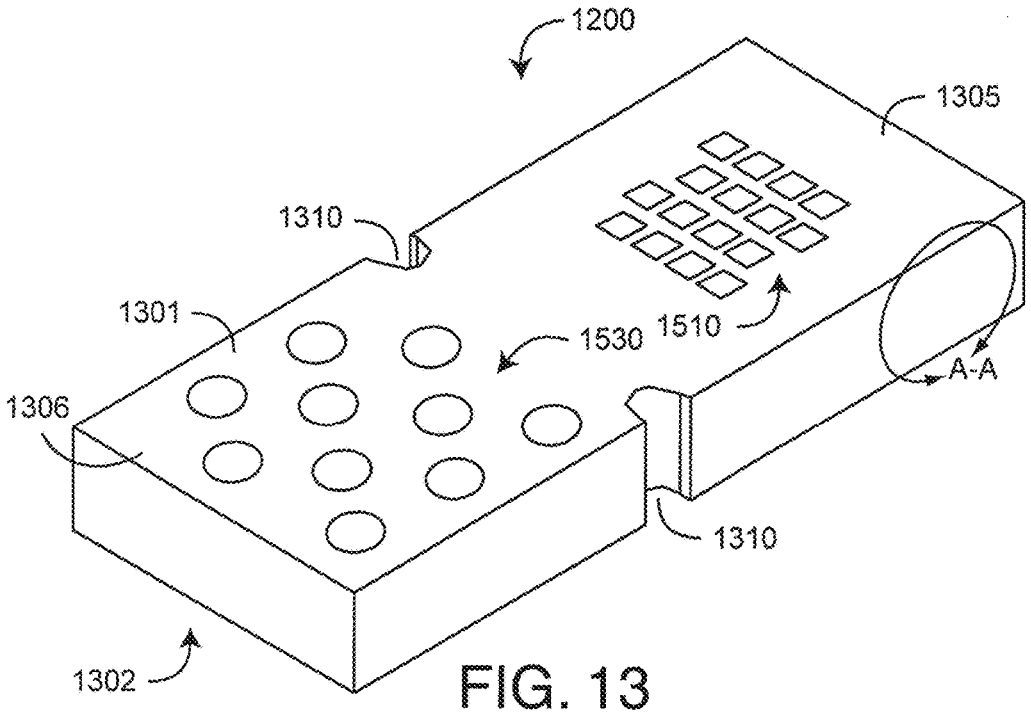

1200
1305
1310
1301
1530
1510
A-A
1306
1310
1302

FIG. 13

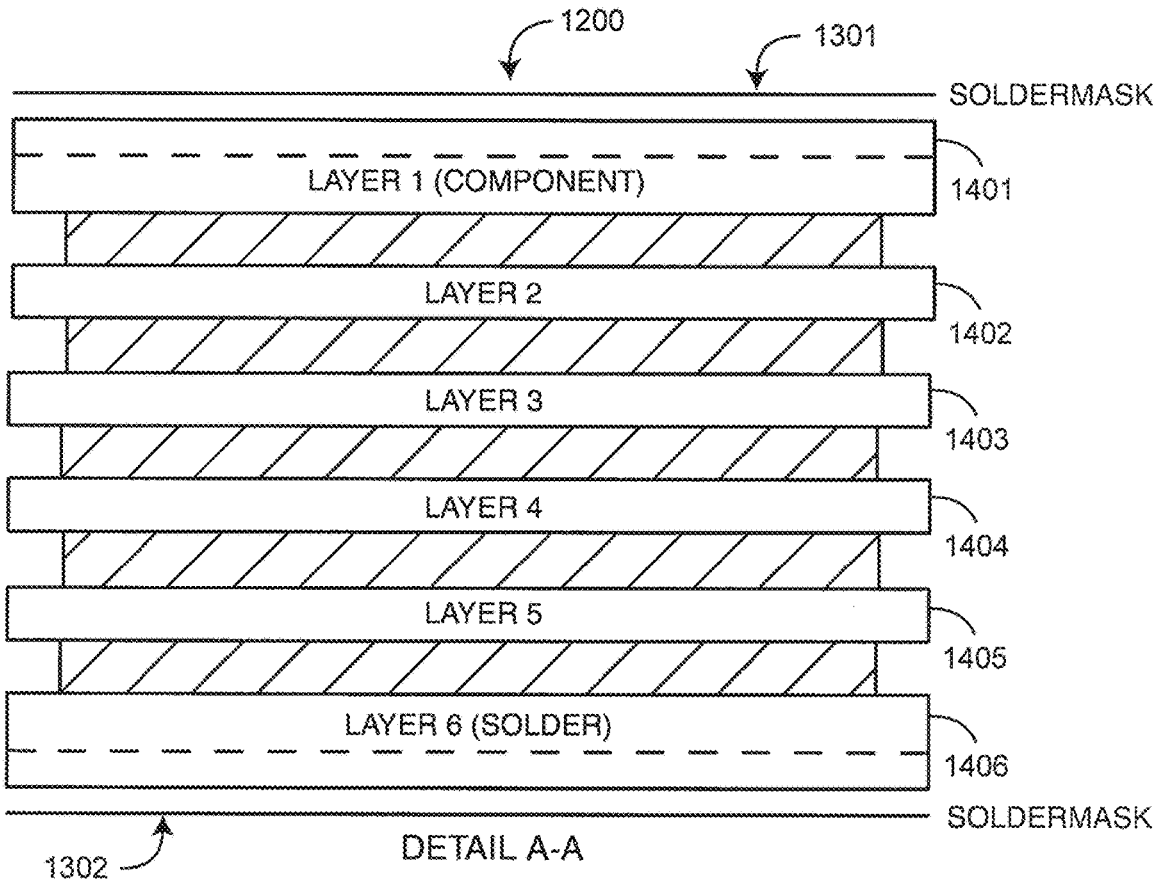

1200
1301
SOLDERMASK
LAYER 1 (COMPONENT)
1401
LAYER 2
1402
LAYER 3
1403
LAYER 4
1404
LAYER 5
1405
LAYER 6 (SOLDER)
1406
SOLDERMASK
1302
DETAIL A-A

FIG. 14

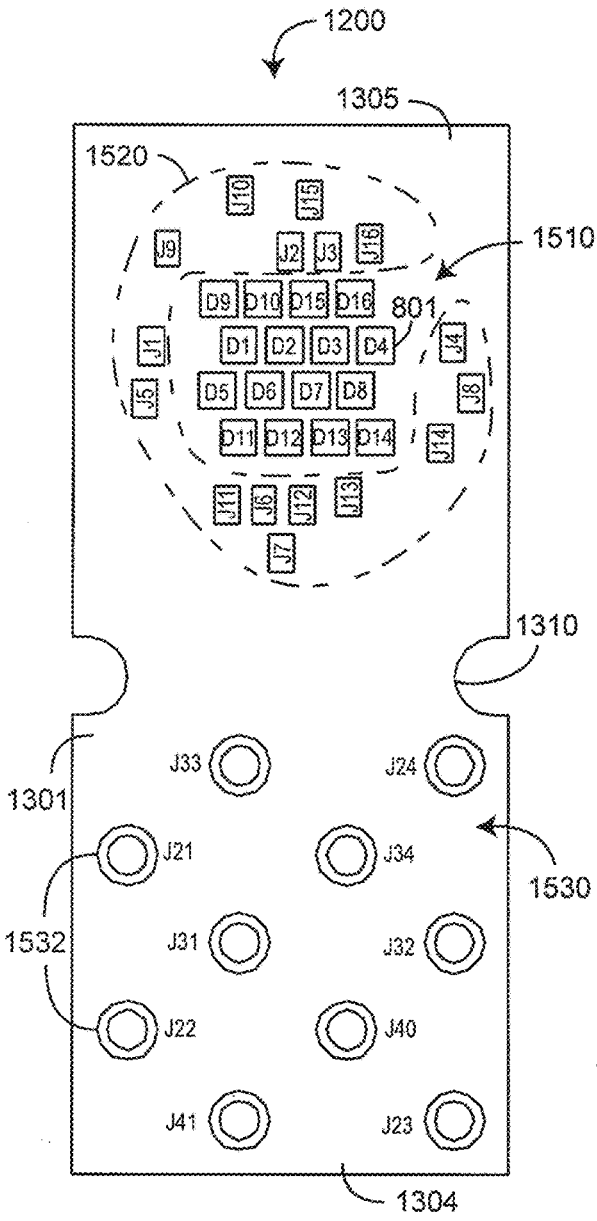

1200
1305
1520
1510
801
1310
1301
1530
1532
1304
J33
J24
J21
J34
J31
J32
J22
J40
J41
J23
D9
D10
D15
D16
D1
D2
D3
D4
D5
D6
D7
D8
D11
D12
D13
D14

FIG. 15

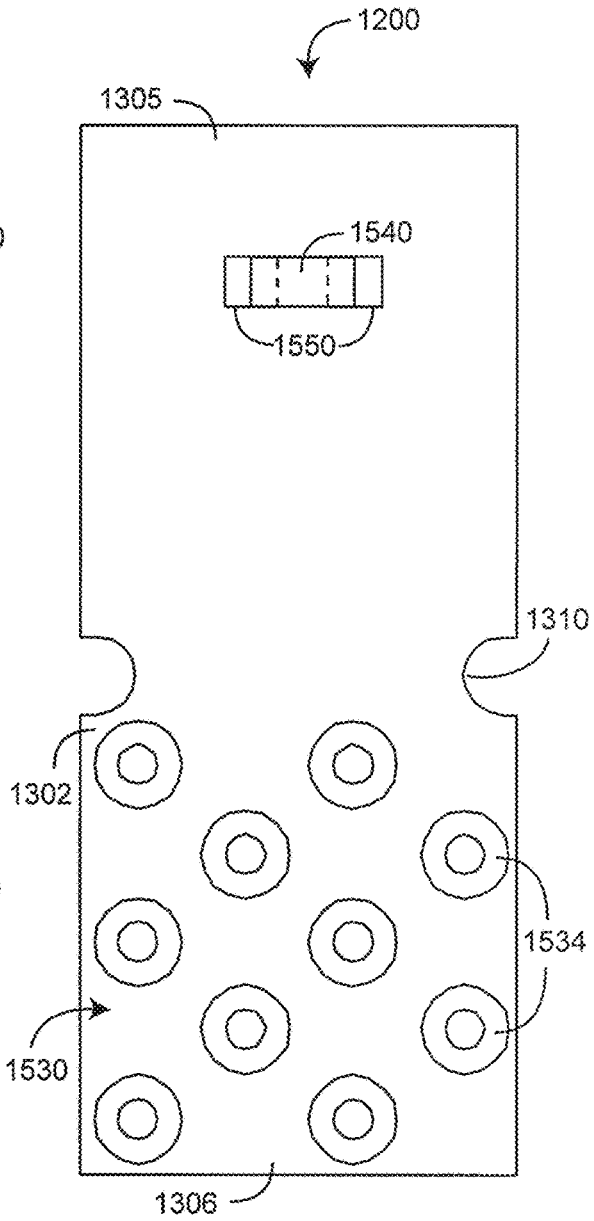

1200
1305
1540
1550
1310
1302
1534
1530
1306

FIG. 16

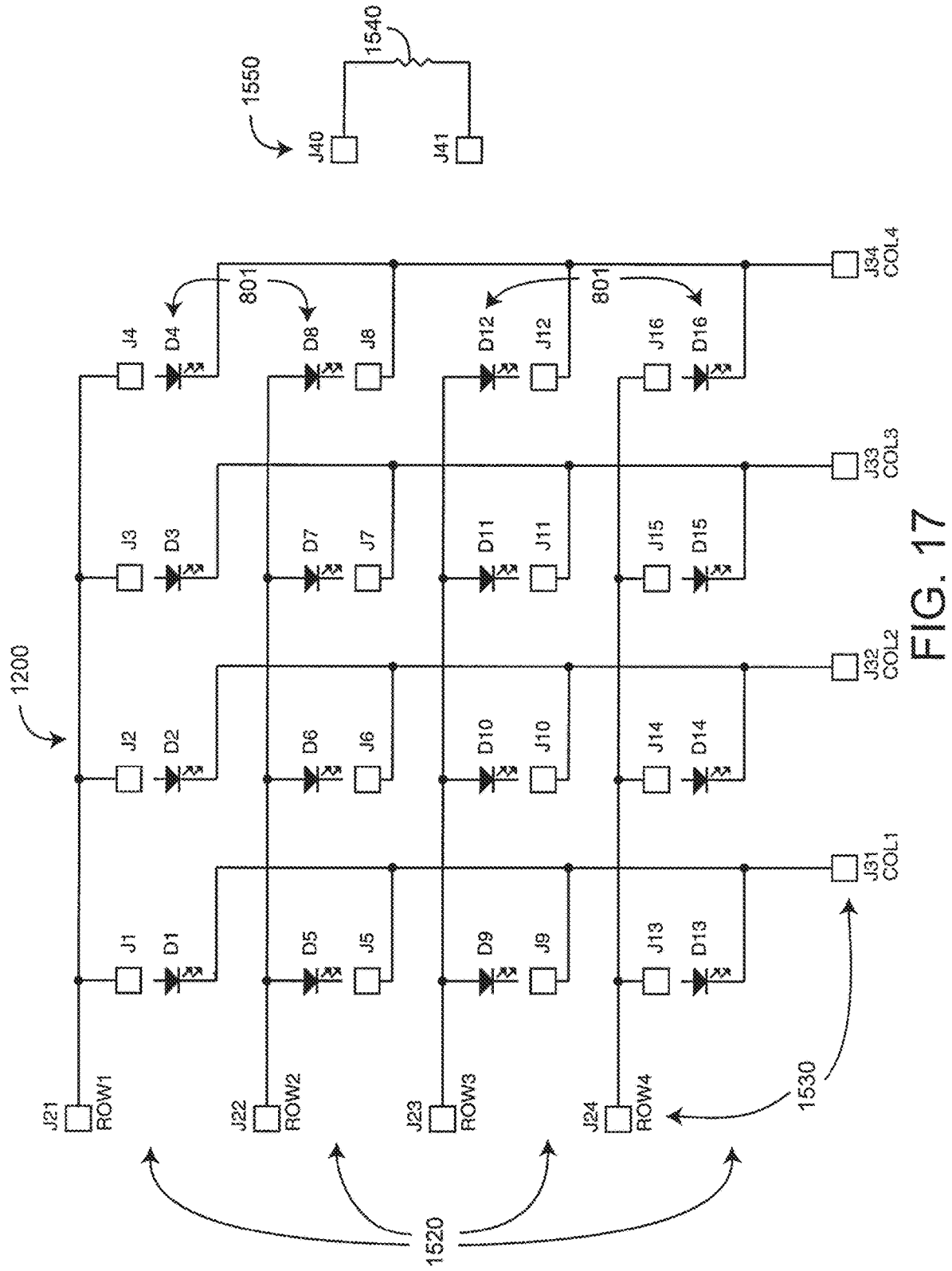

1550
1540
J40
J41
801
801
J4
D4
D8
J8
D12
J12
J16
D16
J34
COL4
J3
D3
D7
J7
D11
J11
J15
D15
J33
COL3
1200
J2
D2
D6
J6
D10
J10
J14
D14
J32
COL2
J1
D1
D5
J5
D9
J9
J13
D13
J31
COL1
J21
ROW1
J22
ROW2
J23
ROW3
J24
ROW4
1530
1520

FIG. 17

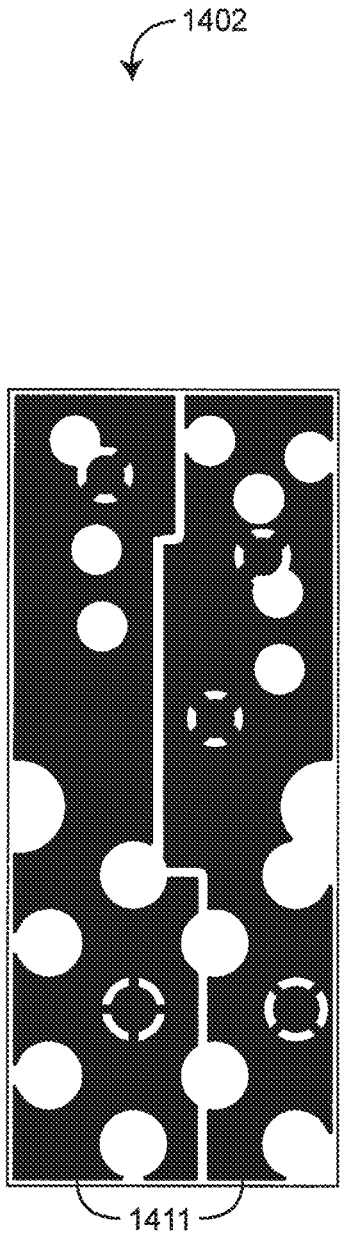


FIG. 18

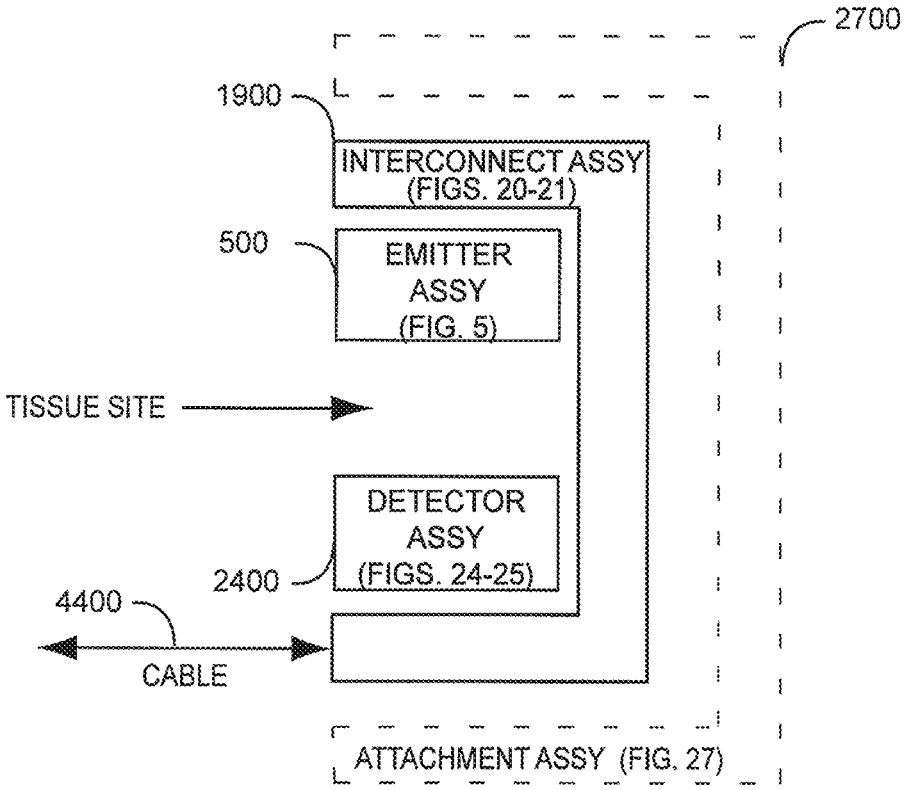

2700
1900
INTERCONNECT ASSY
(FIGS. 20-21)
500
EMITTER
ASSY
(FIG. 5)
TISSUE SITE
DETECTOR
ASSY
(FIGS. 24-25)
2400
4400
CABLE
ATTACHMENT ASSY (FIG. 27)

FIG. 19

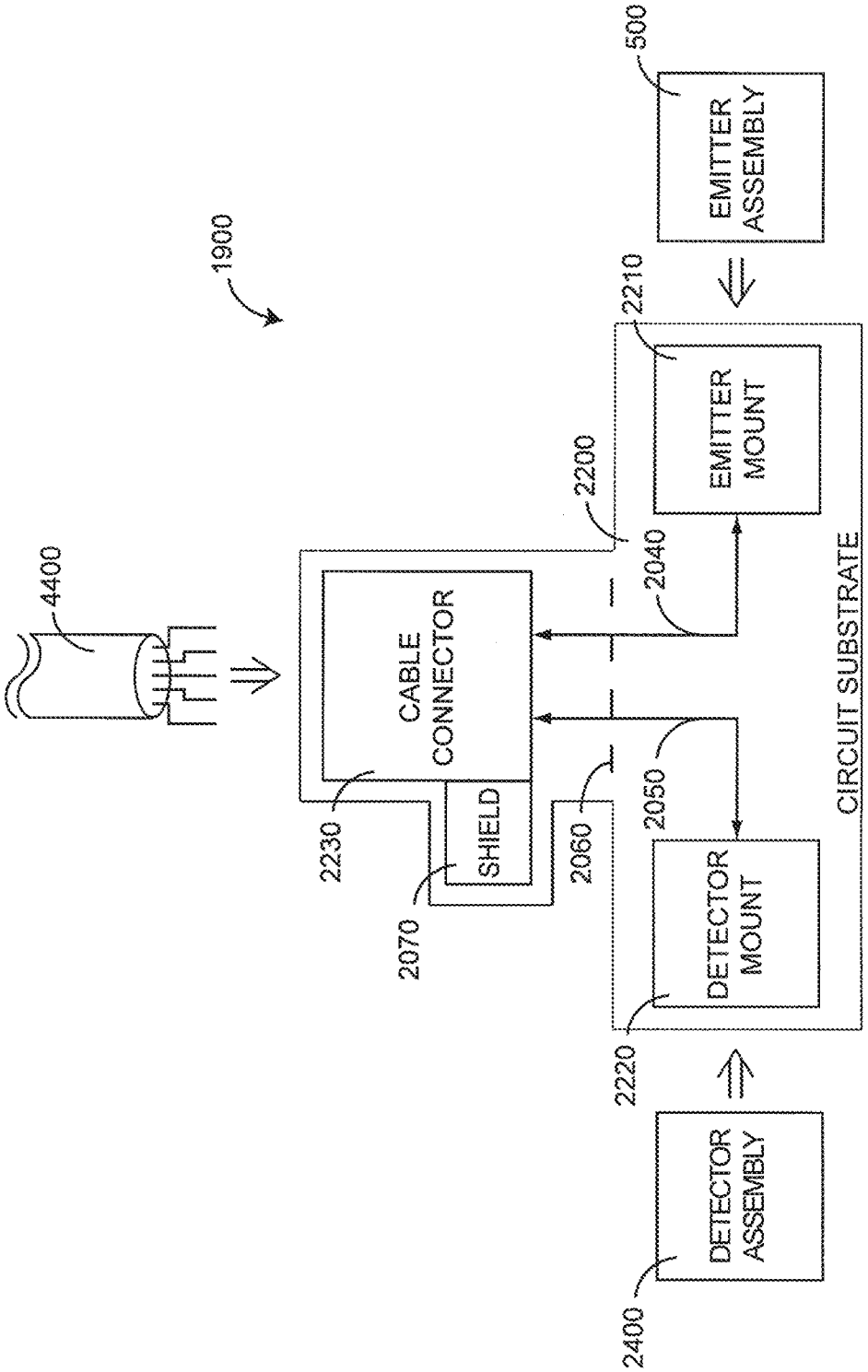

1900
4400
CABLE CONNECTOR
SHIELD
2230
2070
2060
2200
2040
2050
2210
2220
2400
500
EMITTER ASSEMBLY
EMITTER MOUNT
DETECTOR MOUNT
DETECTOR ASSEMBLY
CIRCUIT SUBSTRATE

FIG. 20

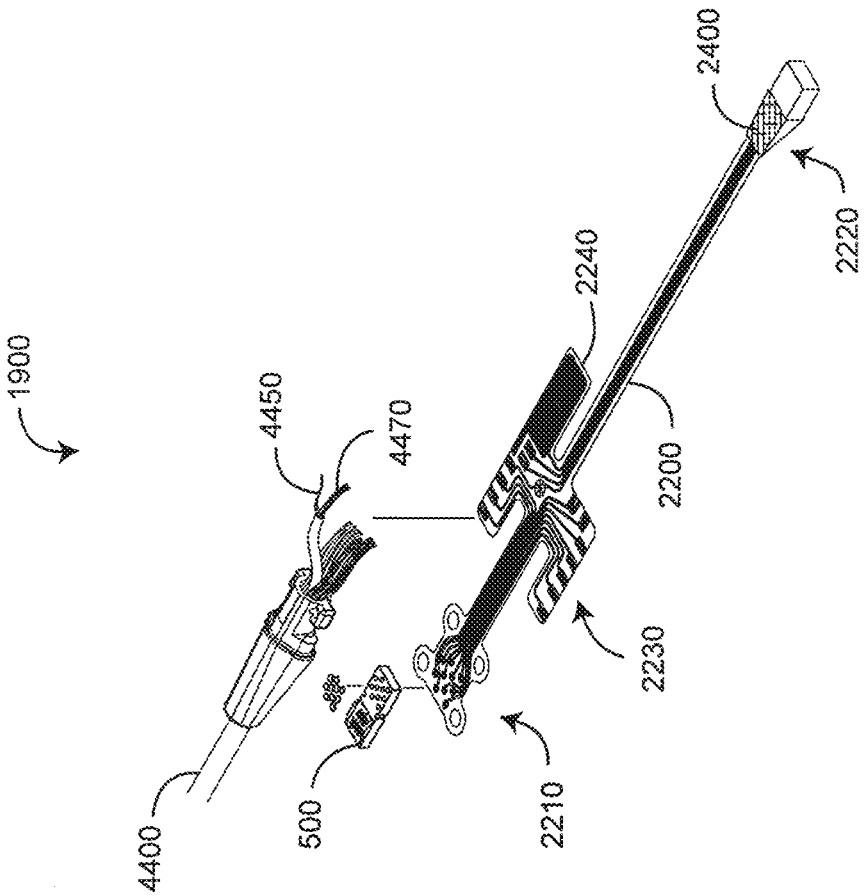


FIG. 21

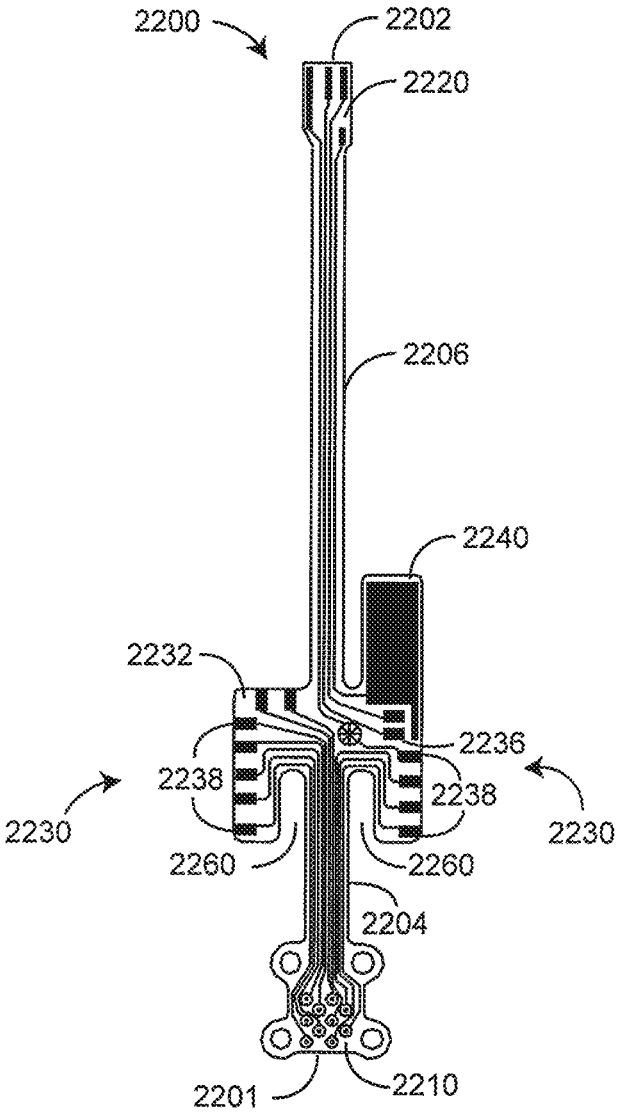

2200
2202
2220
2206
2240
2232
2236
2238
2238
2230
2230
2260
2260
2204
2201
2210

FIG. 22

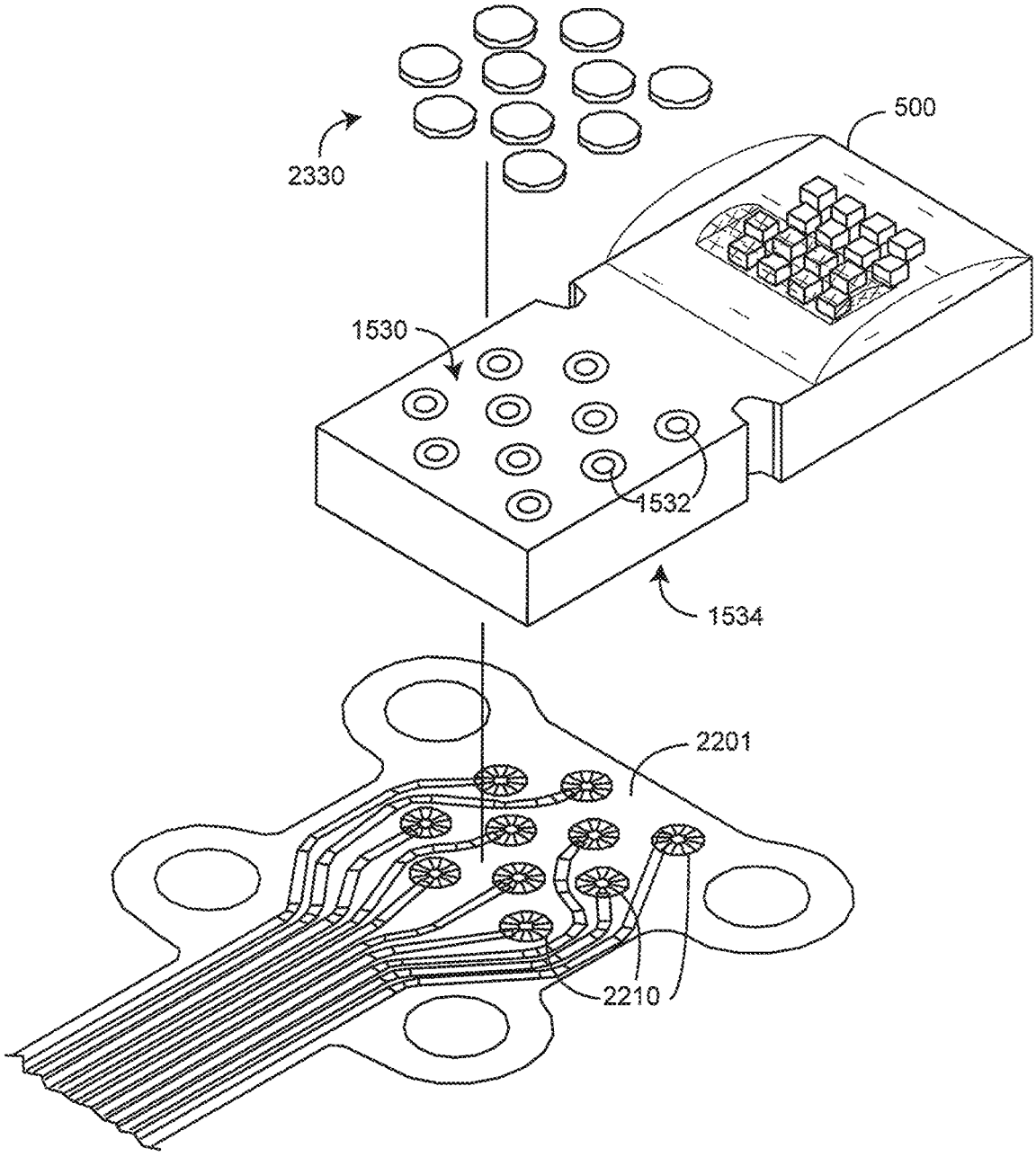


FIG. 23

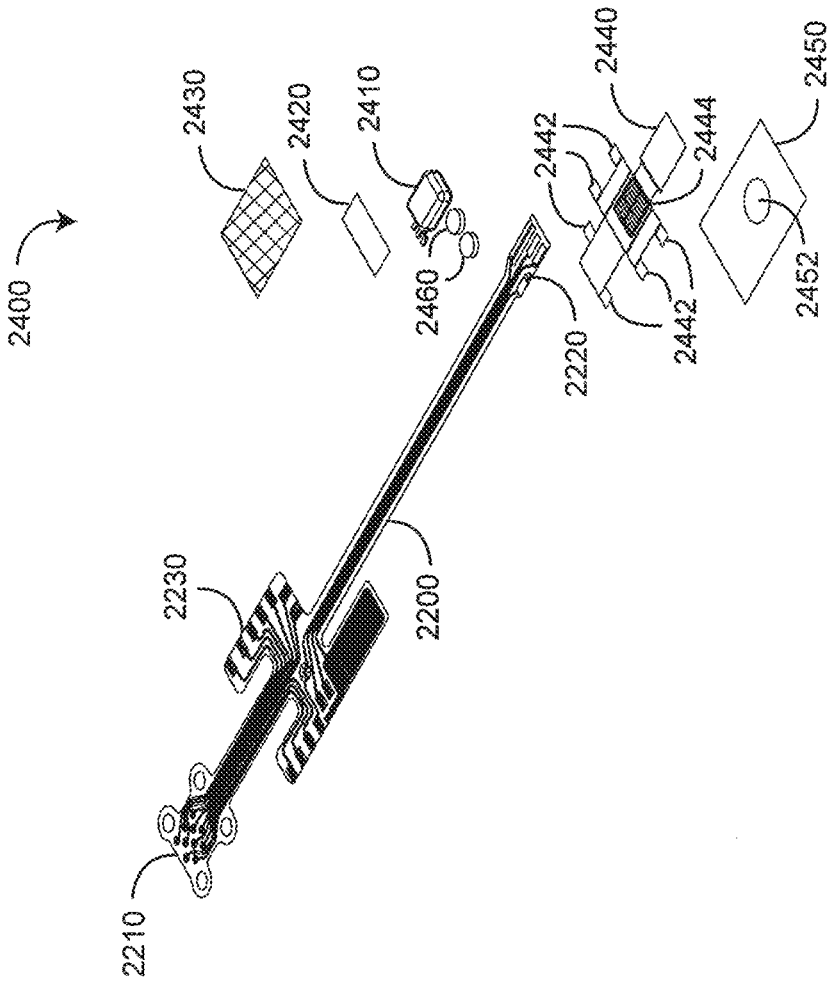

2400
2430
2420
2410
2460
2440
2442
2444
2450
2452
2220
2442
2230
2200
2210

FIG. 24

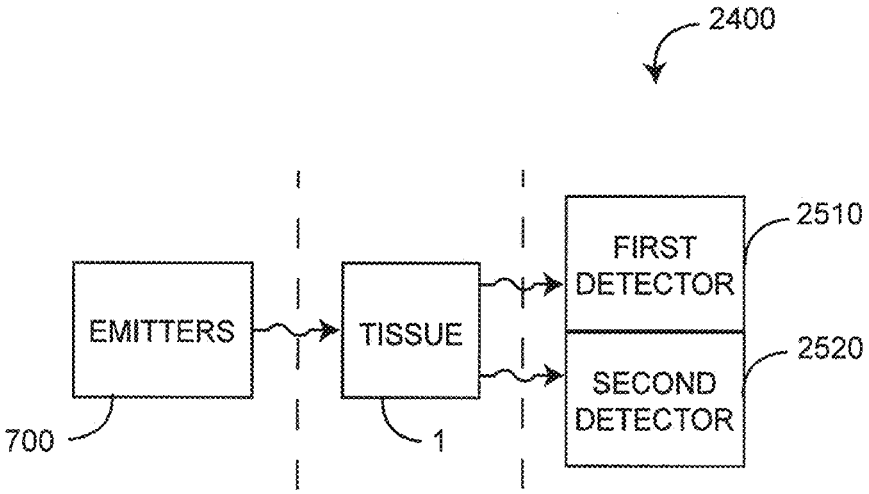

2400
EMITTERS
TISSUE
FIRST DETECTOR
SECOND DETECTOR
2510
2520
700
1

FIG. 25

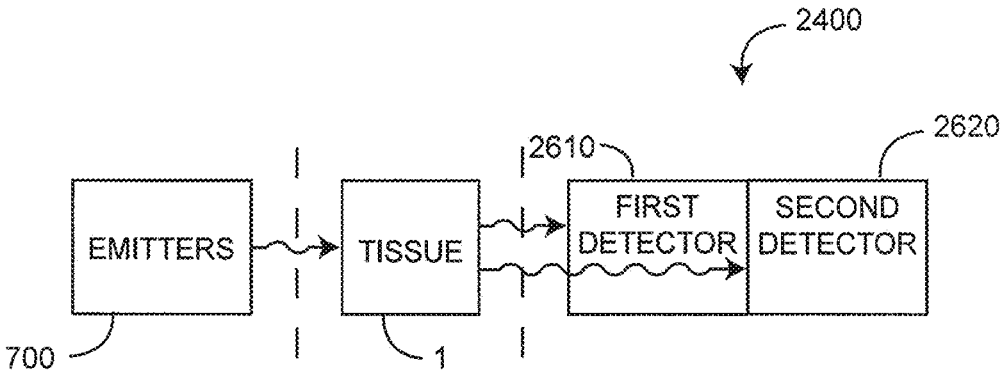

2400
2610
2620
EMITTERS
TISSUE
FIRST DETECTOR
SECOND DETECTOR
700
1

FIG. 26

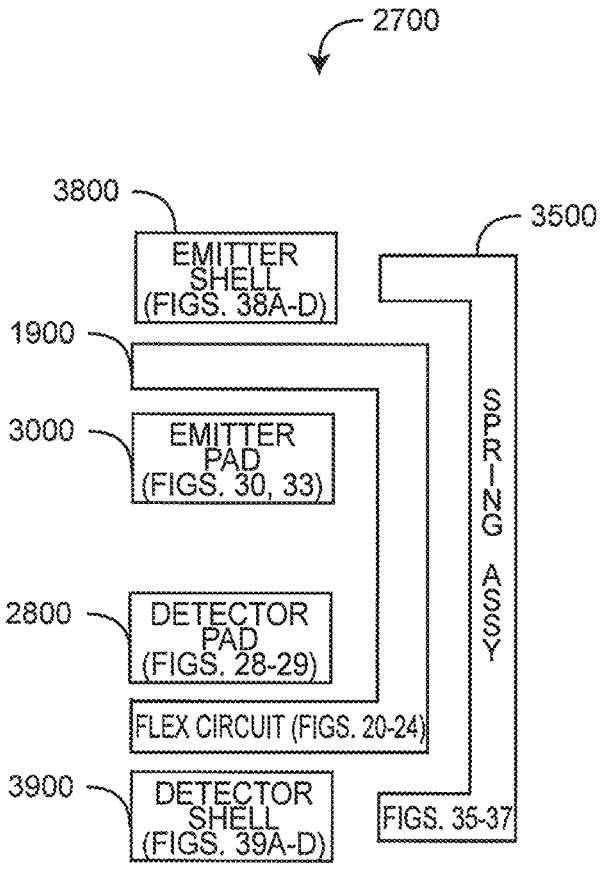

2700
3800
EMITTER SHELL (FIGS. 38A-D)
3500
1900
3000
EMITTER PAD (FIGS. 30, 33)
SPRING ASSY
2800
DETECTOR PAD (FIGS. 28-29)
FLEX CIRCUIT (FIGS. 20-24)
3900
DETECTOR SHELL (FIGS. 39A-D)
FIGS. 35-37

FIG. 27

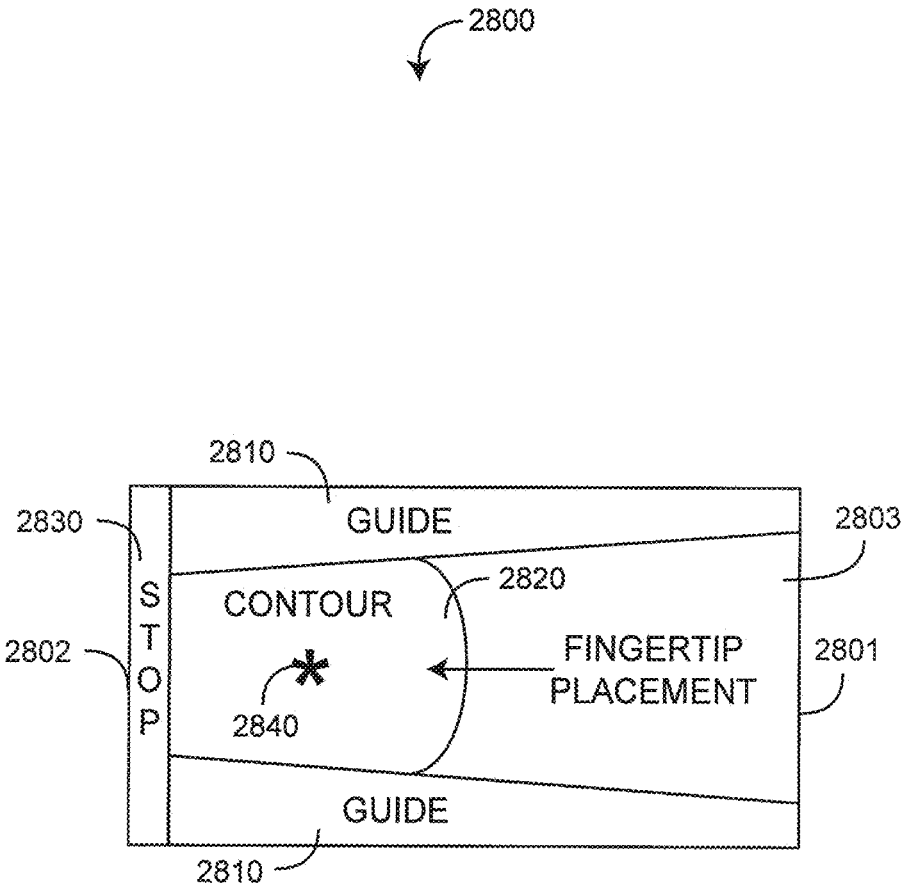

2800
2810
2830
GUIDE
2803
STOP
CONTOUR
2820
2802
FINGERTIP
PLACEMENT
2801
2840
GUIDE
2810

FIG. 28

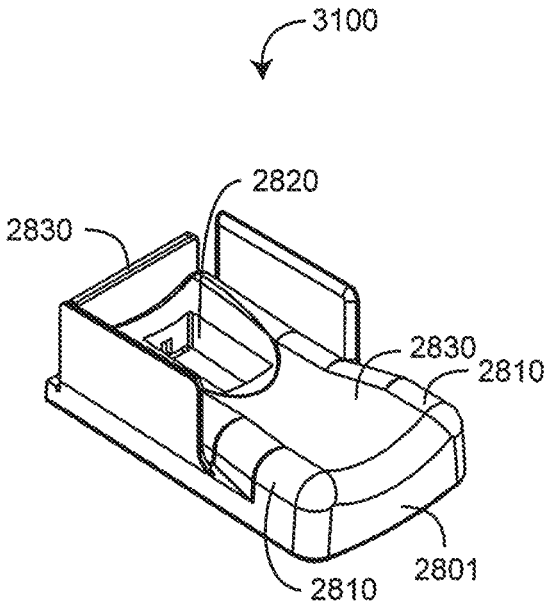


FIG. 29A

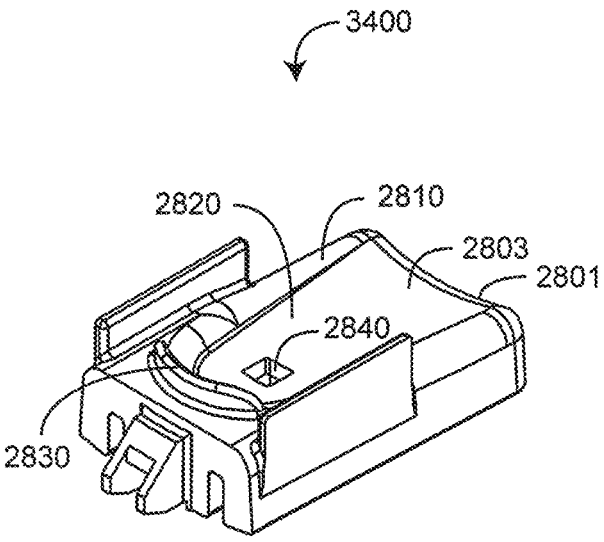


FIG. 29B

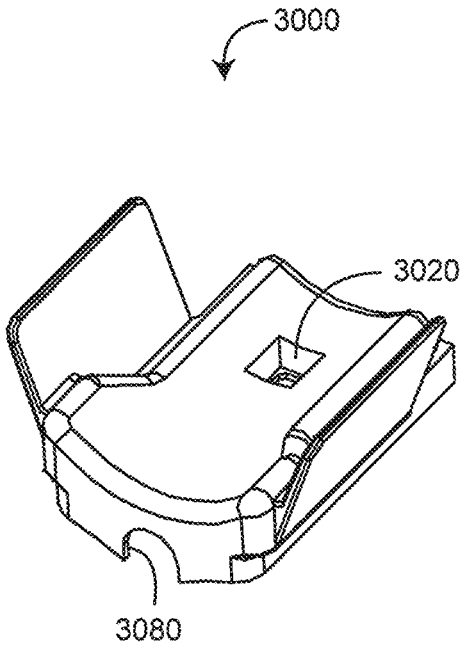


FIG. 30A

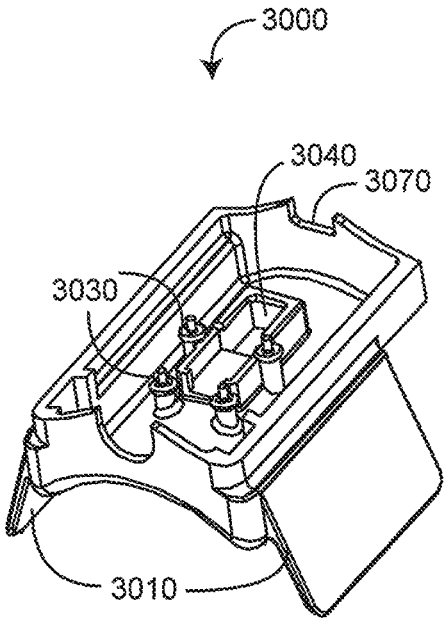


FIG. 30B

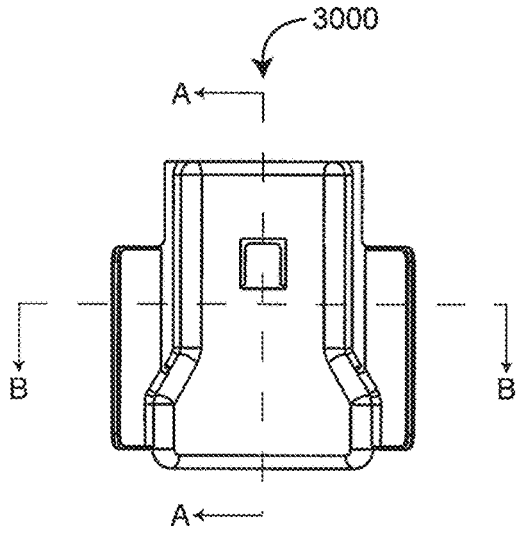


FIG. 30C

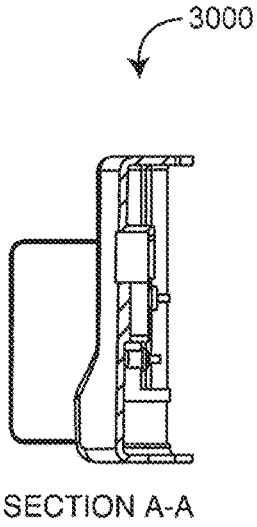


FIG. 30F

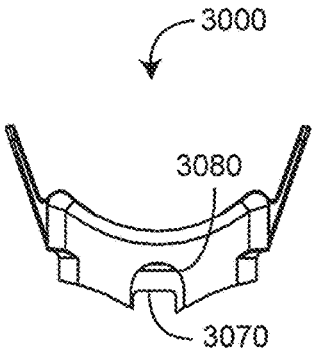


FIG. 30D

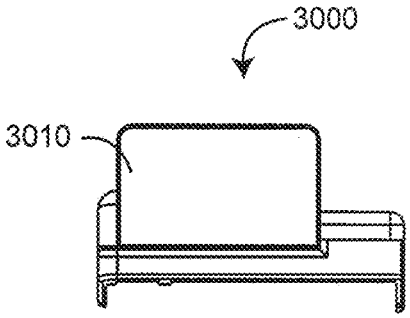


FIG. 30G

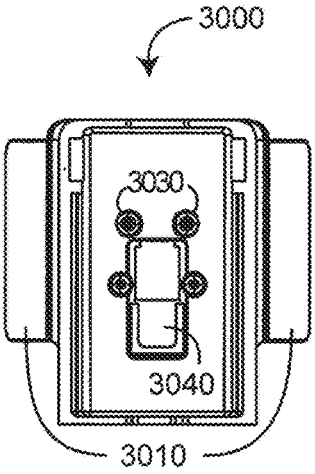


FIG. 30E

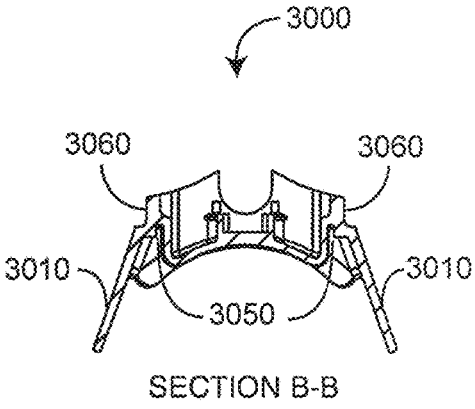


FIG. 30H

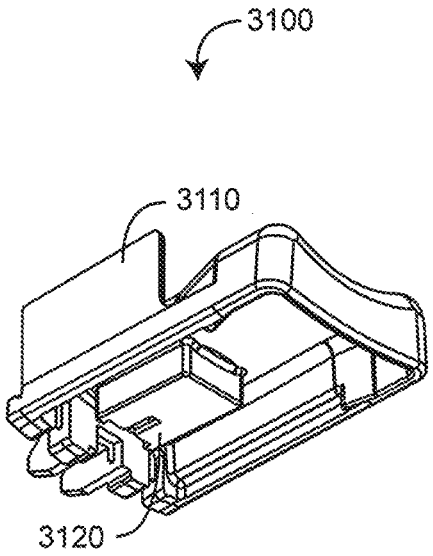


FIG. 31A

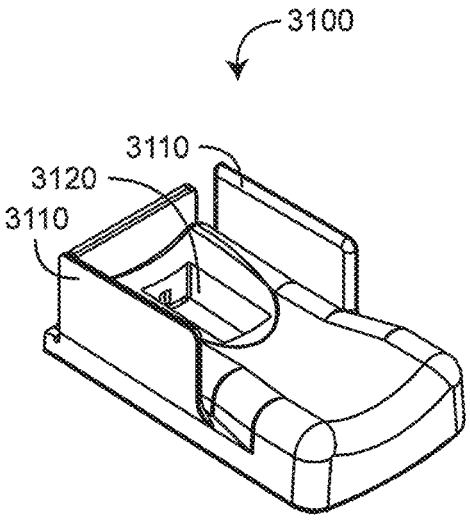


FIG. 31B

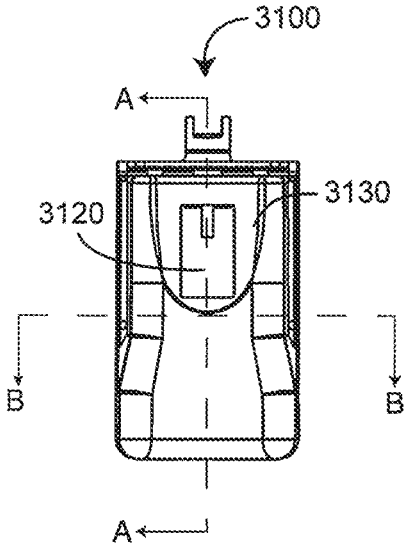
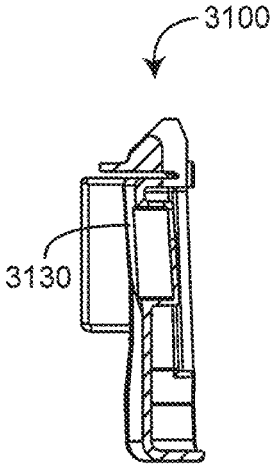


FIG. 31C



SECTION A-A

FIG. 31F

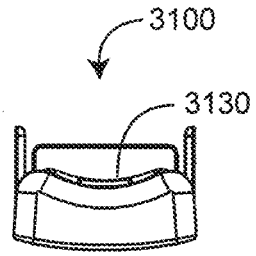


FIG. 31D

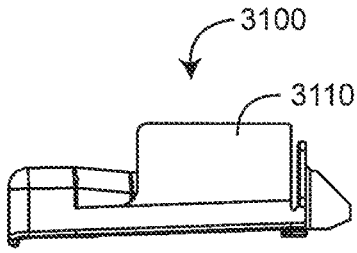


FIG. 31G

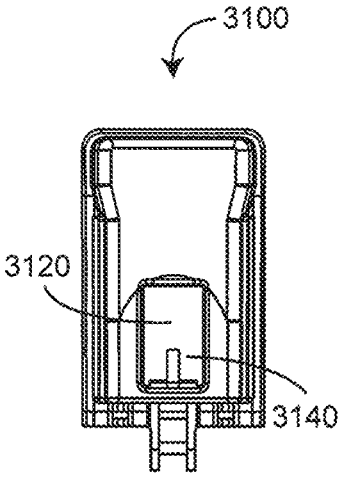
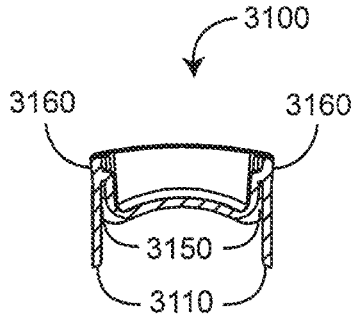


FIG. 31E



SECTION B-B

FIG. 31H

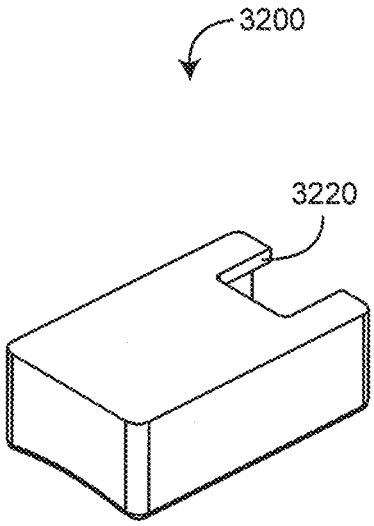


FIG. 32A

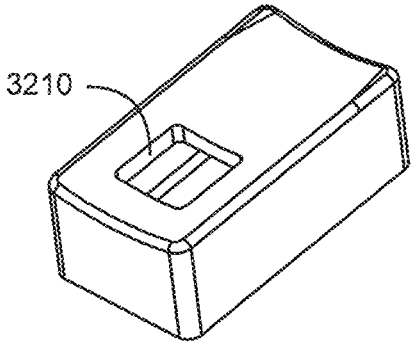


FIG. 32B

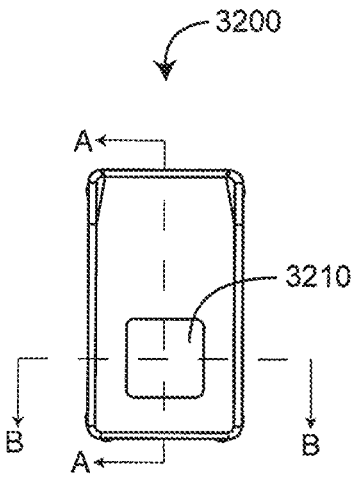


FIG. 32C

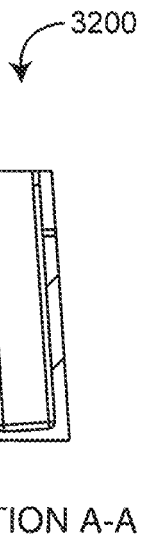


FIG. 32F

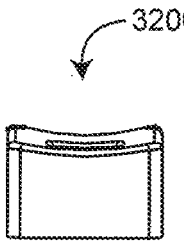


FIG. 32D

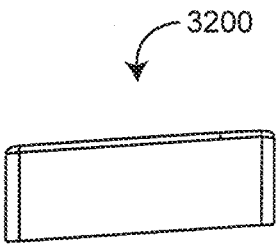


FIG. 32G

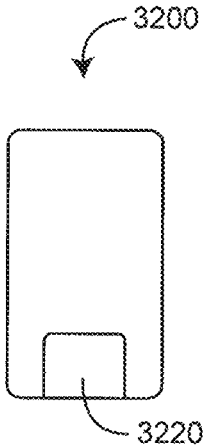


FIG. 32E

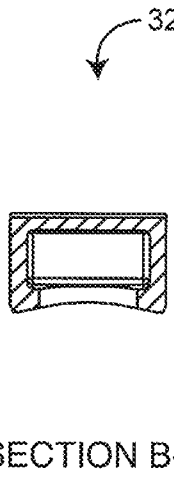


FIG. 32H

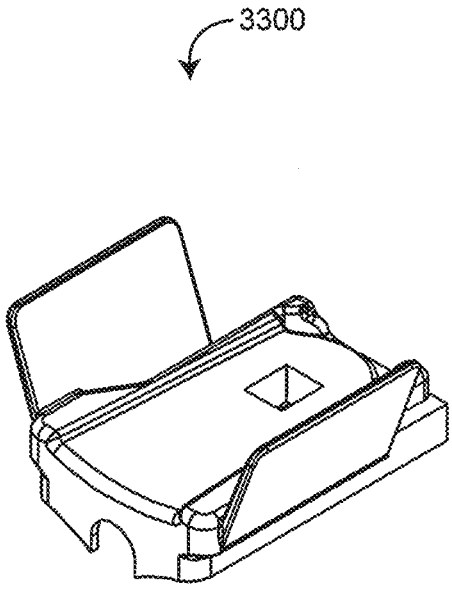


FIG. 33A

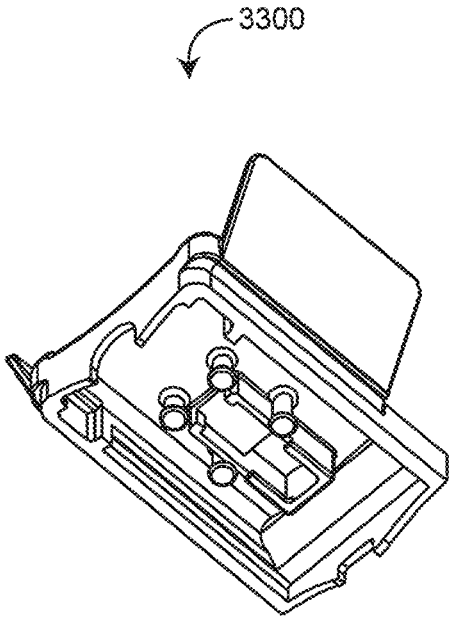


FIG. 33B

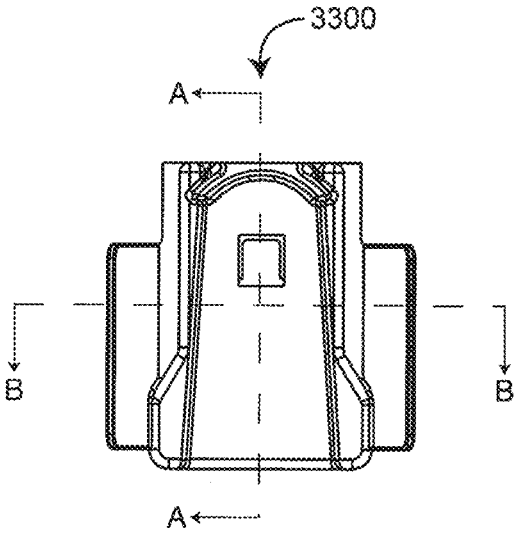


FIG. 33C

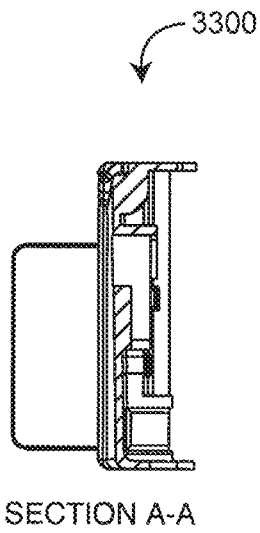


FIG. 33F

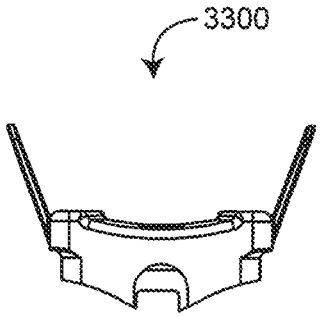


FIG. 33D

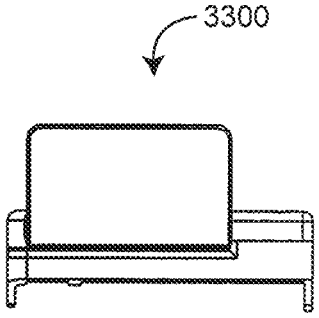


FIG. 33G

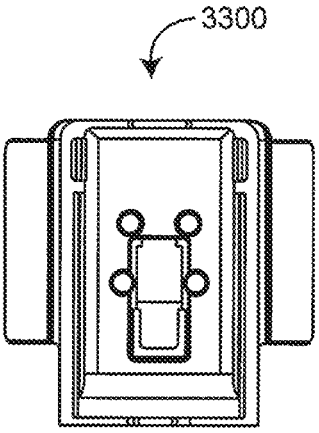


FIG. 33E

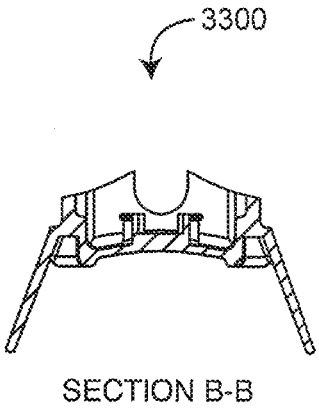


FIG. 33H

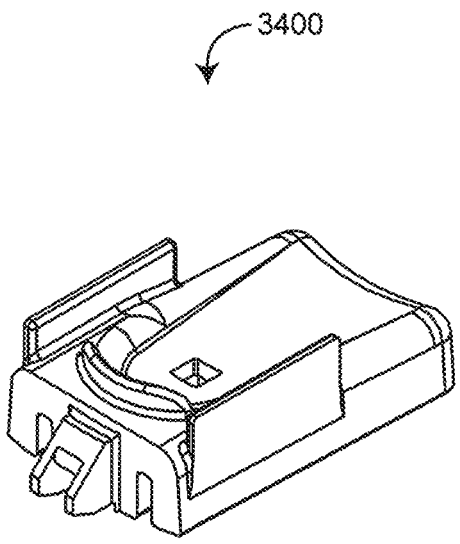


FIG. 34A

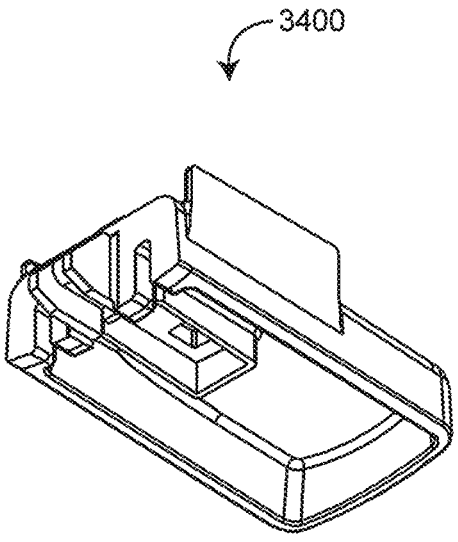


FIG. 34B

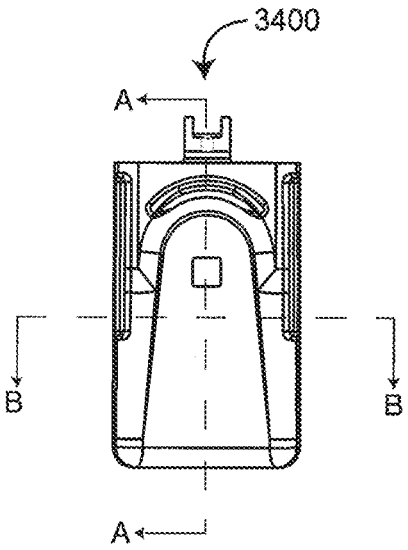


FIG. 34C

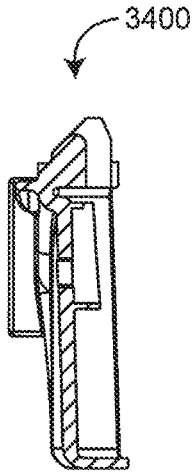


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FIG. 34F

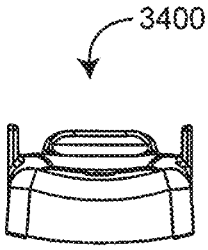


FIG. 34D

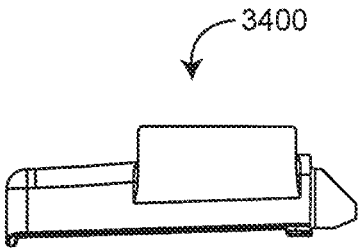


FIG. 34G

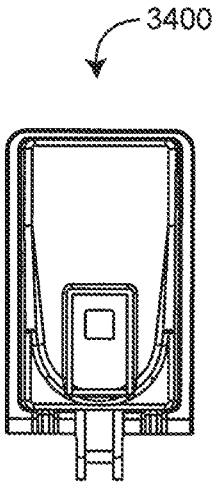
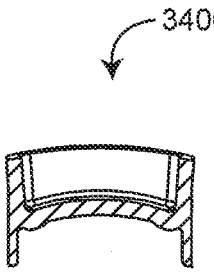


FIG. 34E



SECTION B-B

FIG. 34H

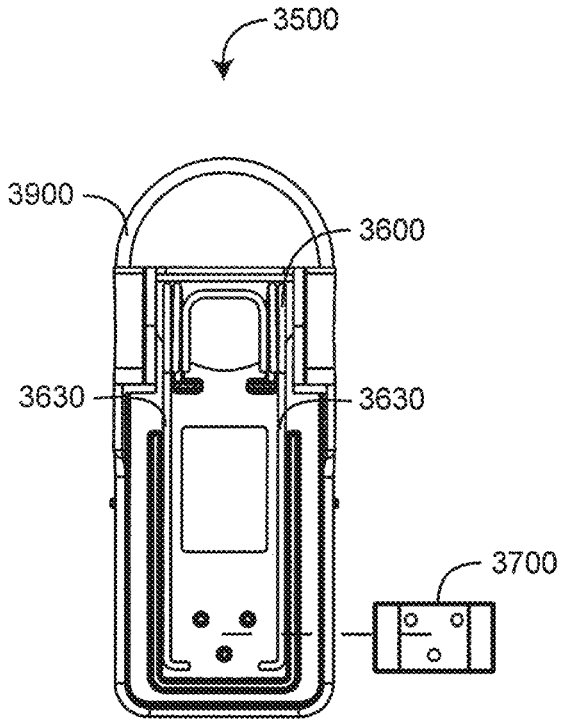


FIG. 35A

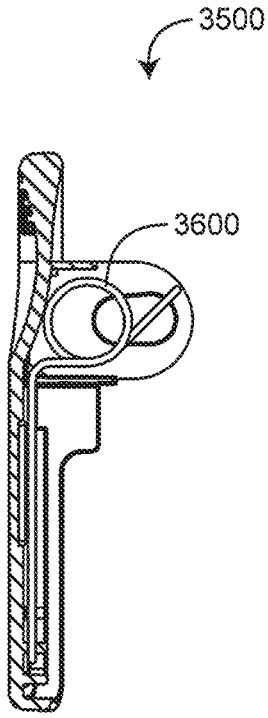


FIG. 35B

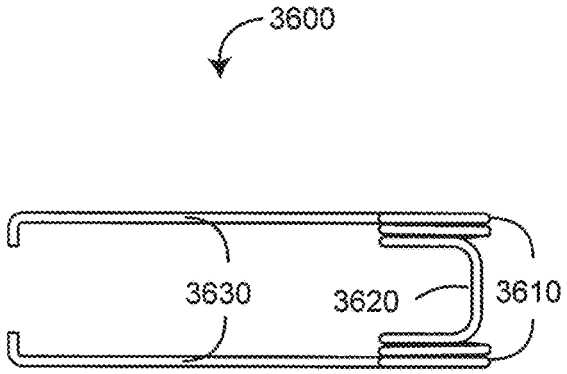


FIG. 36A

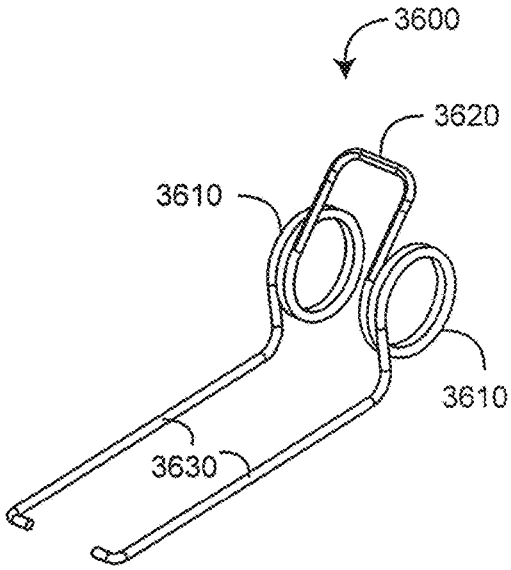


FIG. 36B

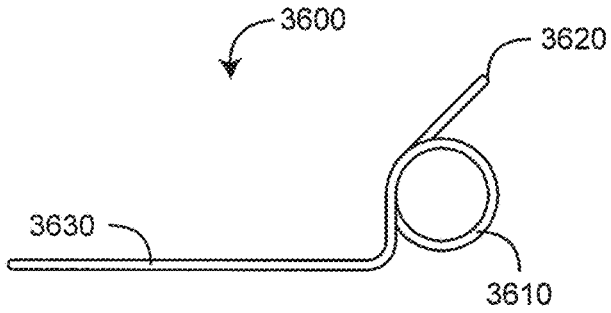


FIG. 36C

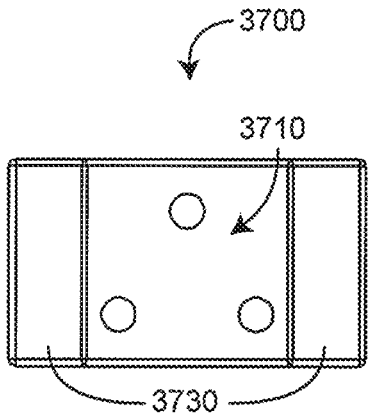


FIG. 37A

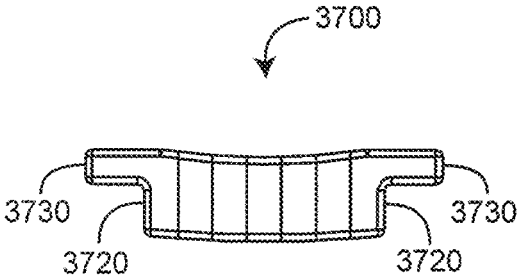


FIG. 37B

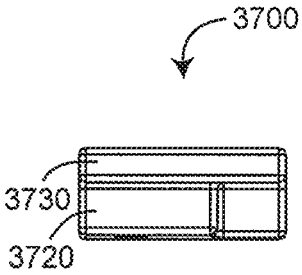


FIG. 37D

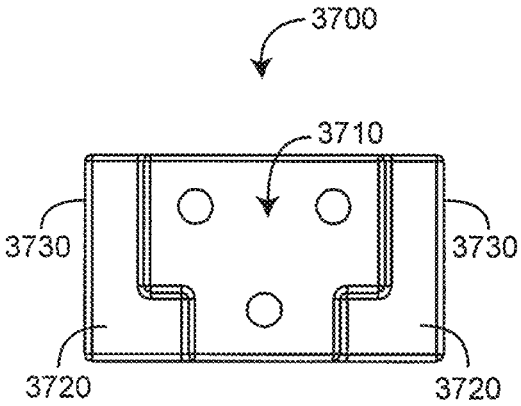


FIG. 37C

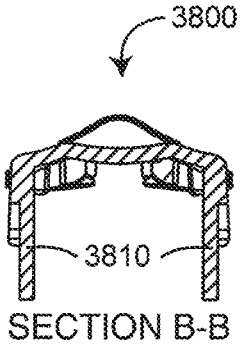


FIG. 38A

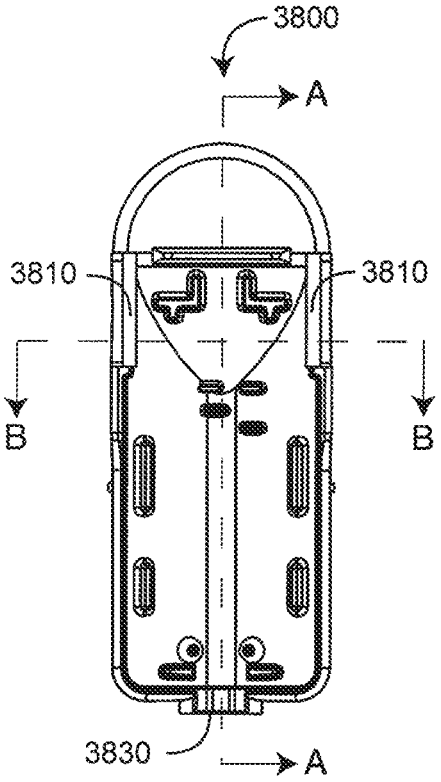


FIG. 38B

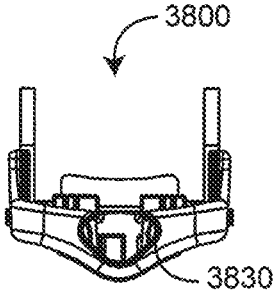


FIG. 38C

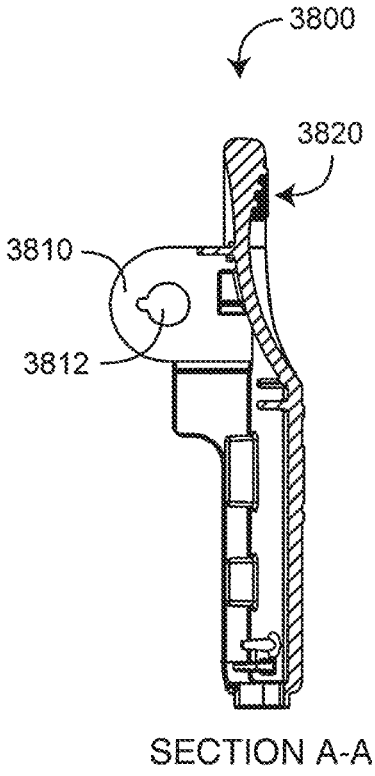


FIG. 38D

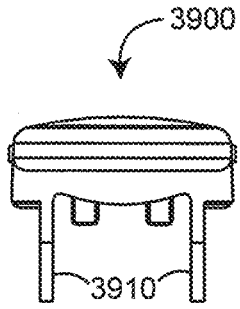


FIG. 39A

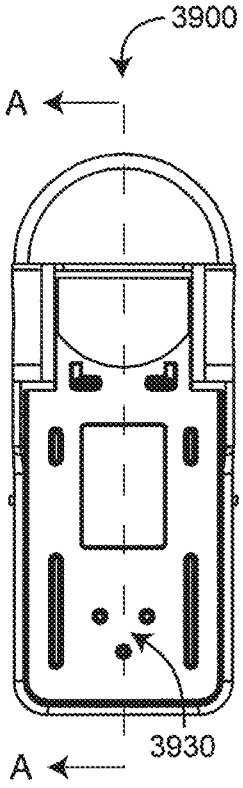


FIG.39B

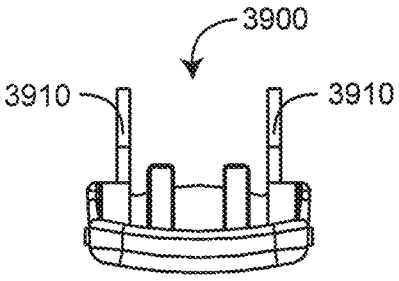


FIG. 39C

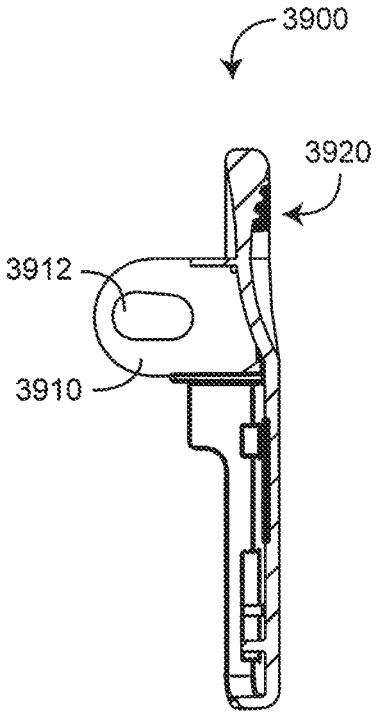


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FIG. 39D

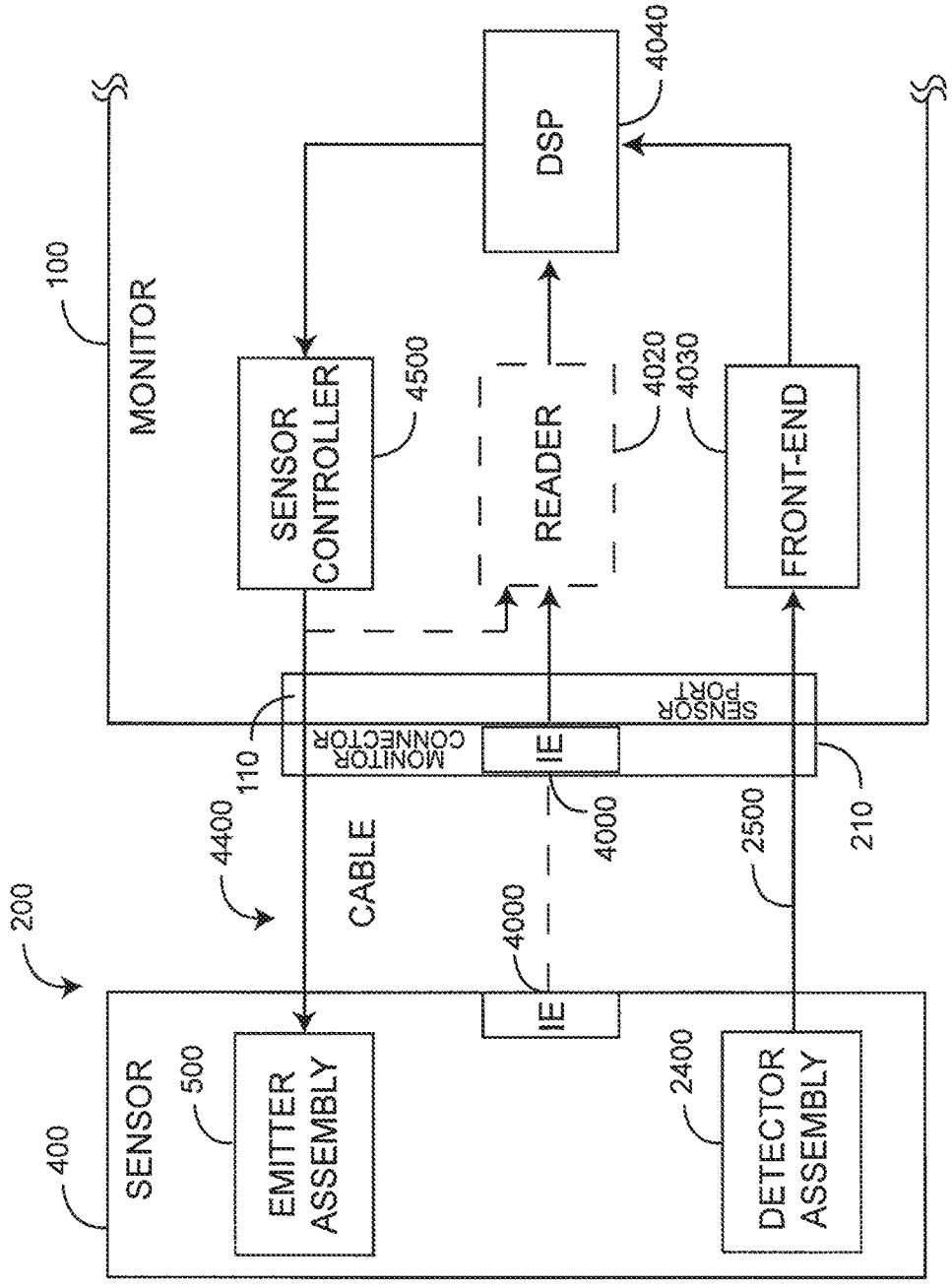
100
MONITOR
DSP
4040
SENSOR CONTROLLER
4500
READER
4020
4030
FRONT-END
SENSOR PORT
MONITOR CONNECTOR
IE
110
210
4400
CABLE
4000
2500
200
4000
IE
SENSOR
400
500
EMITTER ASSEMBLY
2400
DETECTOR ASSEMBLY

FIG. 40

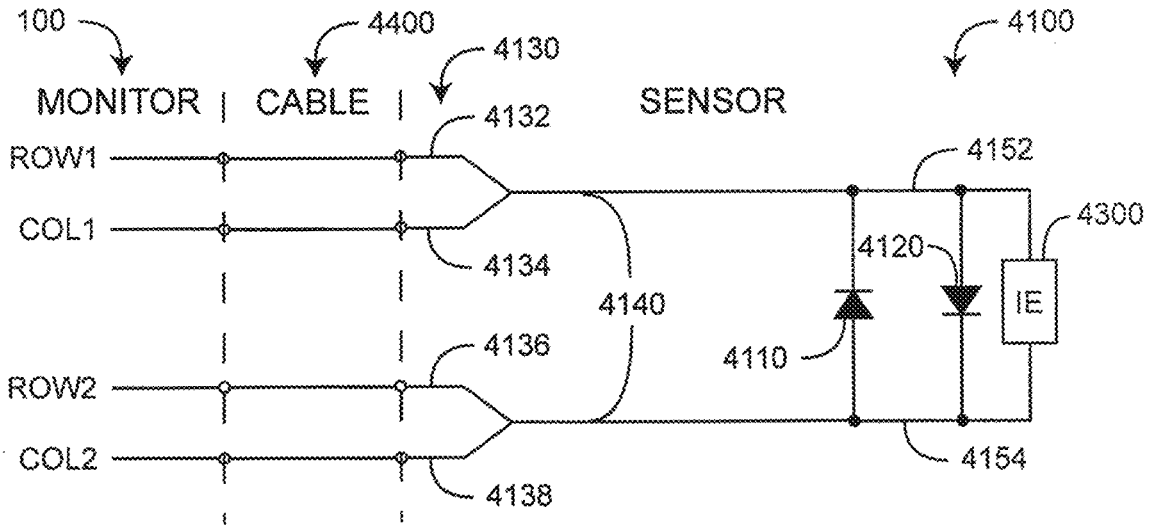

FIG. 41A

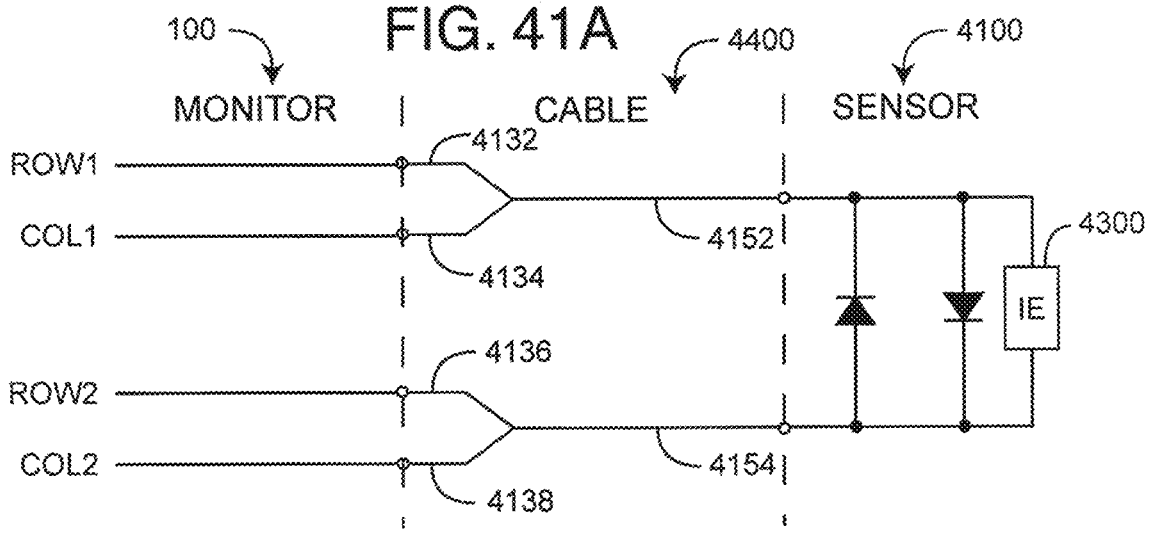

FIG. 41B

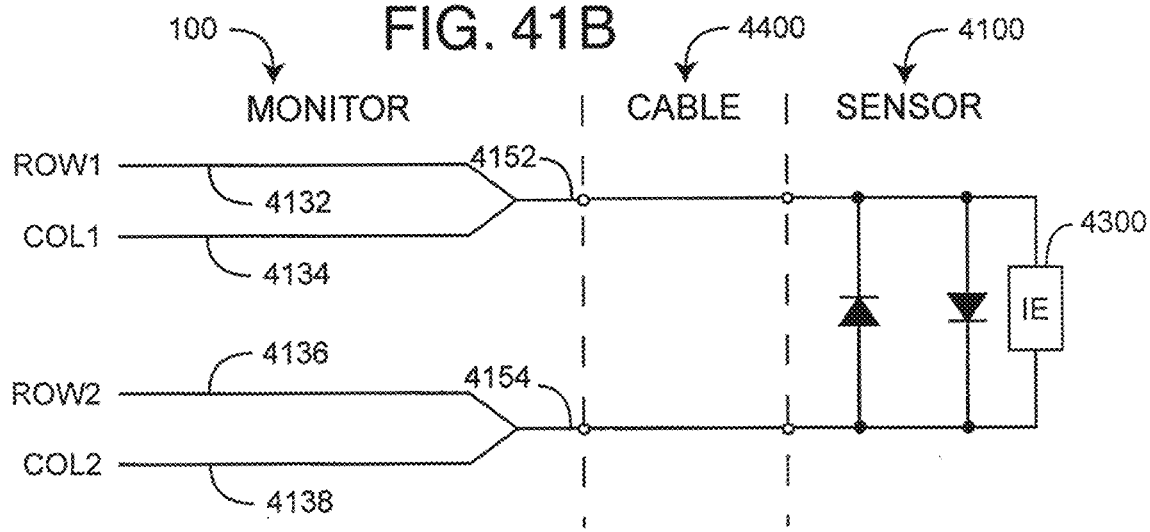

FIG. 41C

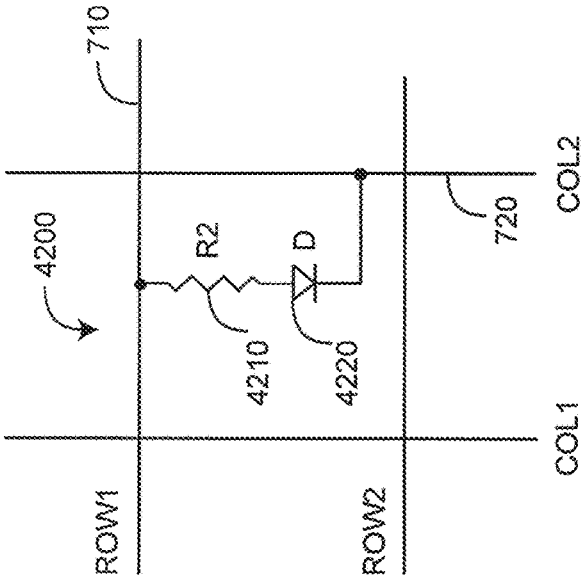

FIG. 42

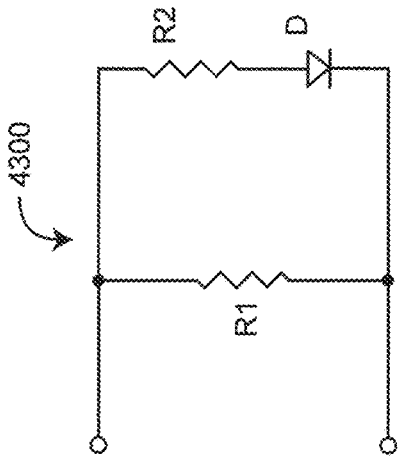

FIG. 43C

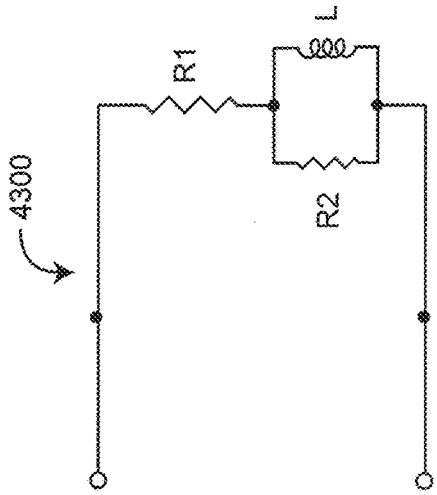

FIG. 43B

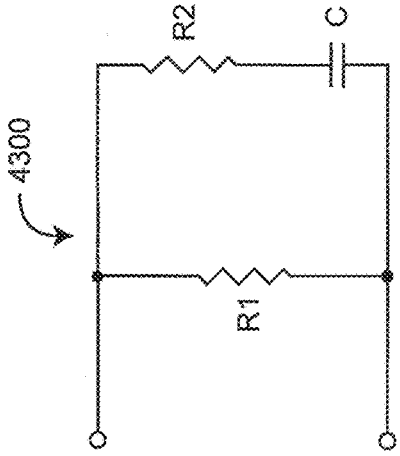

FIG. 43A

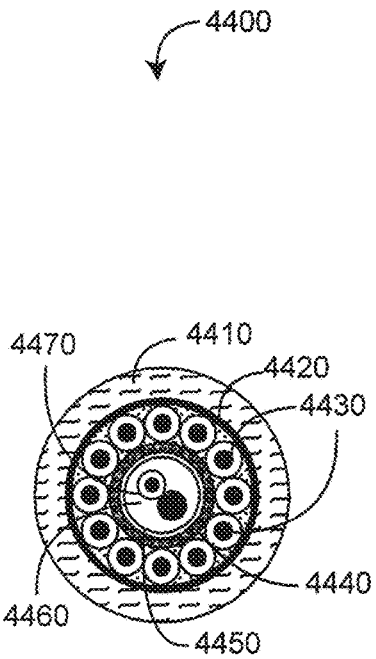

FIG. 44A

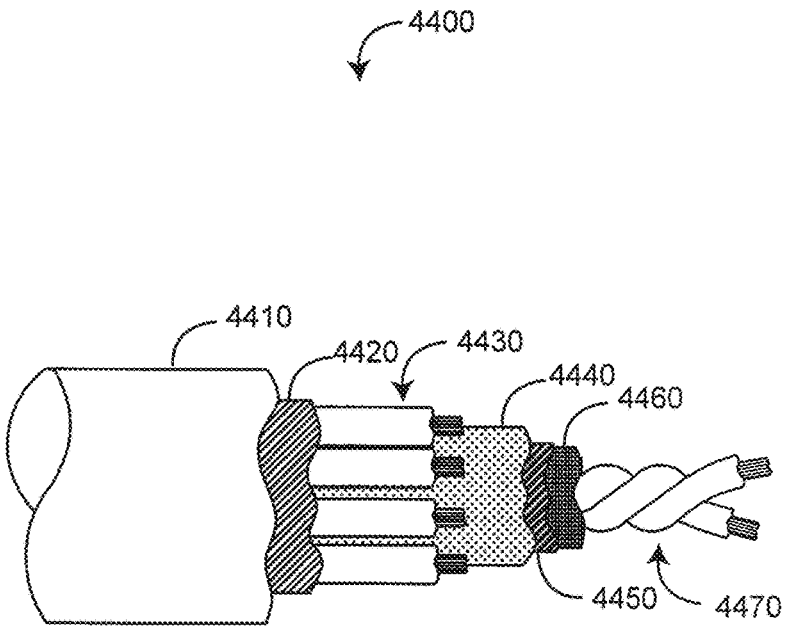

FIG. 44B

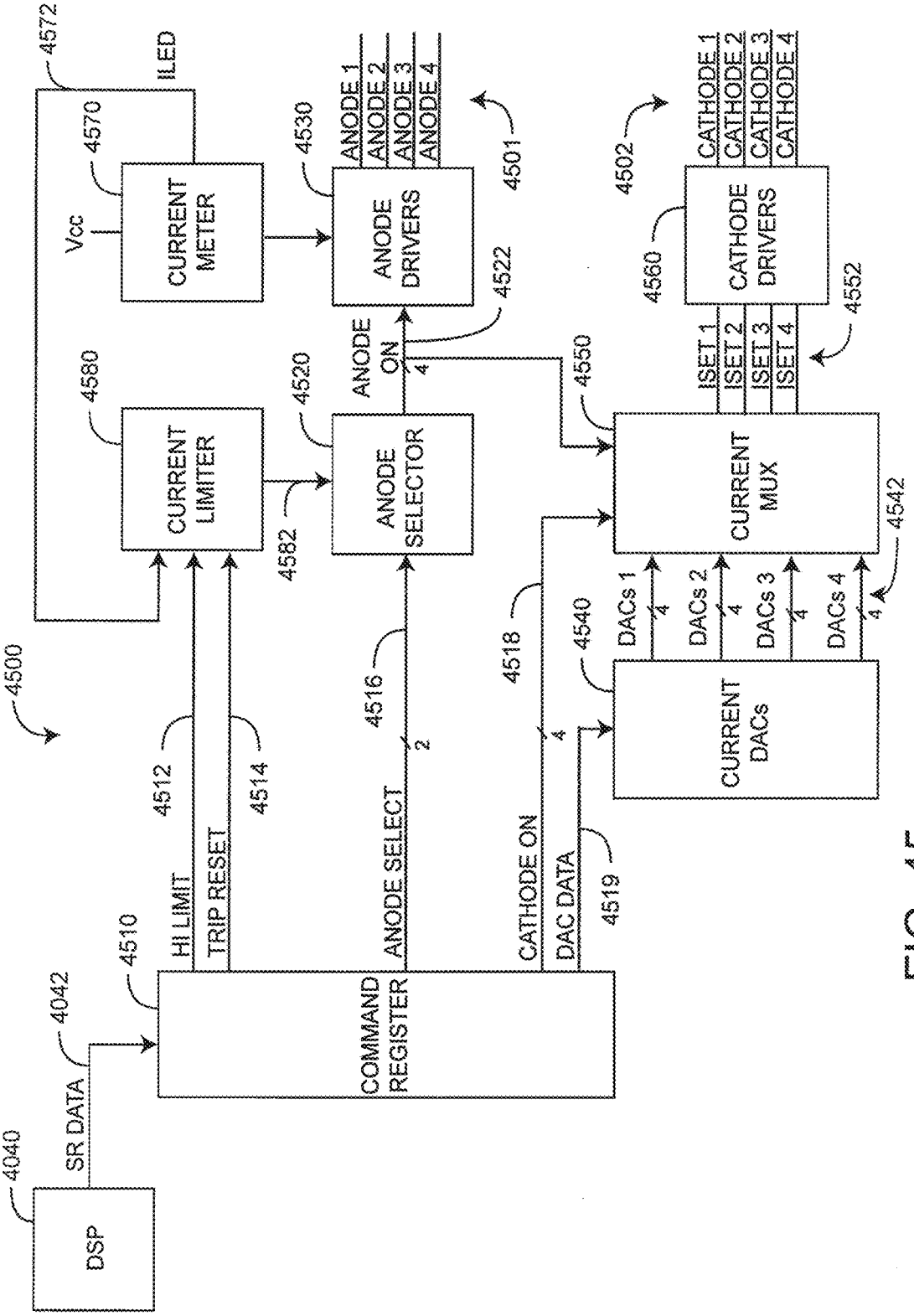
4572
ILED
4570
Vcc
CURRENT METER
4530
ANODE 1
ANODE 2
ANODE 3
ANODE 4
ANODE DRIVERS
4501
4502
CATHODE 1
CATHODE 2
CATHODE 3
CATHODE 4
4560
CATHODE DRIVERS
4552
4522
4580
CURRENT LIMITER
4520
ANODE SELECTOR
ANODE ON
4
4550
ISET 1
ISET 2
ISET 3
ISET 4
CURRENT MUX
4542
4582
4516
2
4518
4
4540
DACs 1
DACs 2
DACs 3
DACs 4
CURRENT DACs
4500
4512
4514
HI LIMIT
TRIP RESET
ANODE SELECT
CATHODE ON
DAC DATA
4519
4510
COMMAND REGISTER
4042
SR DATA
4040
DSP

FIG. 45

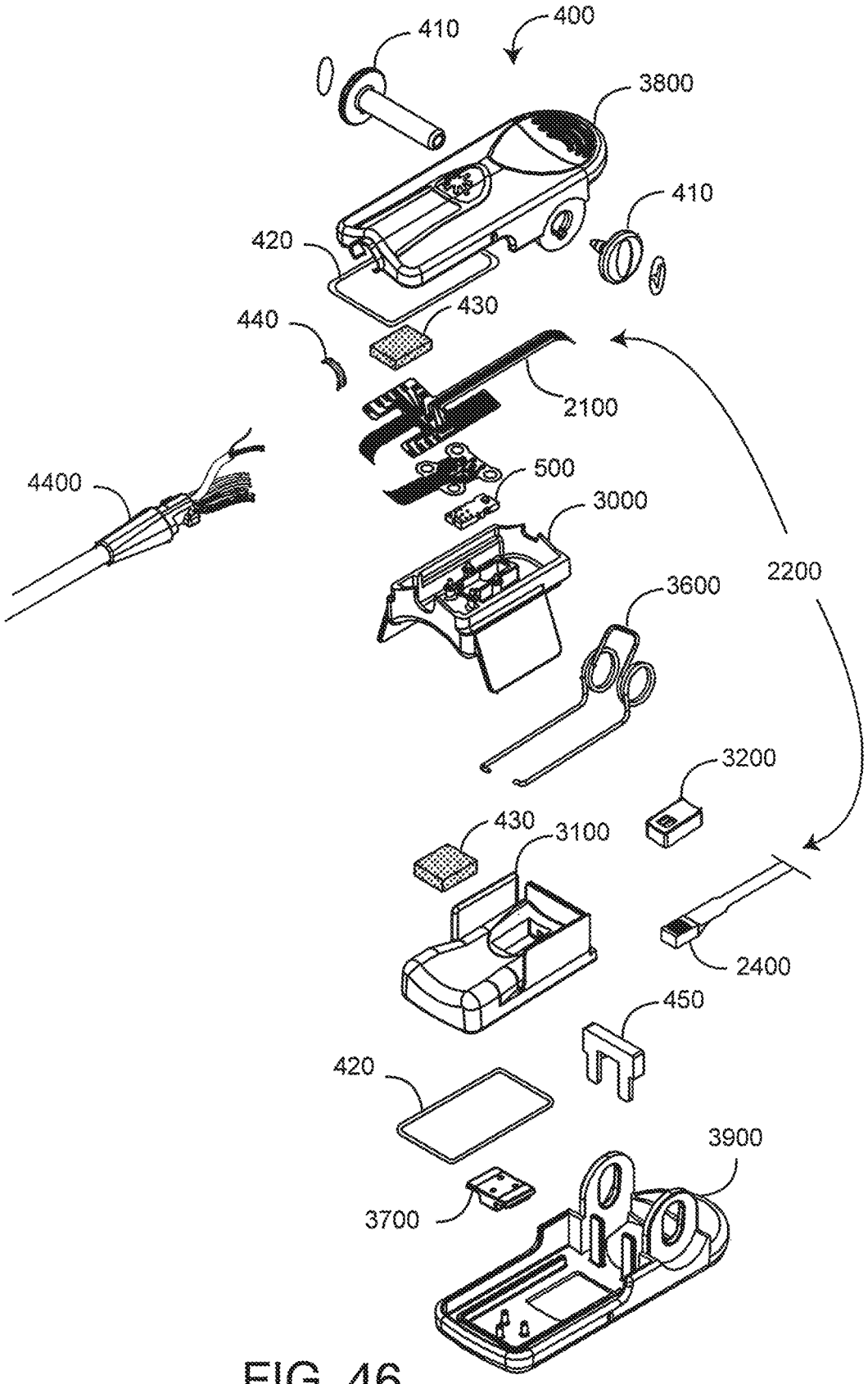
410
400
3800
410
420
430
440
2100
4400
500
3000
2200
3600
3200
430
3100
2400
450
420
3900
3700

FIG. 46

MULTIPLE WAVELENGTH SENSOR EMITTERS

PRIORITY CLAIM

The present application is a continuation of U.S. patent application Ser. No. 16/437,611, entitled "Multiple Wavelength Sensor Emitters," filed Jun. 11, 2019, which is a continuation of U.S. patent application Ser. No. 15/694,541, entitled "Multiple Wavelength Sensor Emitters," filed Sep. 1, 2017, now issued as U.S. Pat. No. 10,327,683, which is a continuation of U.S. patent application Ser. No. 14/472,760, entitled "Multiple Wavelength Sensor Emitters," filed Aug. 29, 2014, now issued as U.S. Pat. No. 9,750,443, which is a continuation of U.S. patent application Ser. No. 13/776,065, entitled "Multiple Wavelength Sensor Emitters," filed Feb. 25, 2013, now issued as U.S. Pat. No. 8,849,365, which is a continuation of U.S. patent application Ser. No. 12/422,915, entitled "Multiple Wavelength Sensor Emitters," filed Apr. 13, 2009, now issued as U.S. Pat. No. 8,385,996, which is a continuation of U.S. patent application Ser. No. 11/367,013, entitled "Multiple Wavelength Sensor Emitters," filed Mar. 1, 2006, now issued as U.S. Pat. No. 7,764,982, which claims priority benefit to U.S. Provisional Patent App. No. 60/657,596, filed Mar. 1, 2005, entitled "Multiple Wavelength Sensor," U.S. Provisional Patent App. No. 60/657,281, filed Mar. 1, 2005, entitled "Physiological Parameter Confidence Measure," U.S. Provisional Patent App. No. 60/657,268, filed Mar. 1, 2005, entitled "Configurable Physiological Measurement System," and U.S. Provisional Patent App. No. 60/657,759, filed Mar. 1, 2005, entitled "Noninvasive Multi-Parameter Patient Monitor." The present application incorporates each of the foregoing disclosures herein by reference in its entirety and for all purposes.

INCORPORATION BY REFERENCE OF RELATED APPLICATIONS

The present application is related to the following U.S. utility applications:

	App. Ser. No.	Filing Date	Title	Atty Dock.
1	11/367,013	Mar. 1, 2006	Multiple Wavelength Sensor Emitters	MLR.002A
	11/546,932	Oct. 12, 2006	Disposable Wavelength Optical Sensor	MLR.002CP1
2	11/366,995	Mar. 1, 2006	Multiple Wavelength Sensor Equalization	MLR.003A
3	11/366,209	Mar. 1, 2006	Multiple Wavelength Sensor Substrate	MLR.004A
4	11/366,210	Mar. 1, 2006	Multiple Wavelength Sensor Interconnect	MLR.005A
5	11/366,833	Mar. 1, 2006	Multiple Wavelength Sensor Attachment	MLR.006A
6	11/366,997	Mar. 1, 2006	Multiple Wavelength Sensor Drivers	MLR.009A
7	11/367,034	Mar. 1, 2006	Physiological Parameter Confidence Measure	MLR.010A
8	11/367,036	Mar. 1, 2006	Configurable Physiological Measurement System	MLR.011A
9	11/367,033	Mar. 1, 2006	Noninvasive Multi-Parameter Patient Monitor	MLR.012A
10	11/367,014	Mar. 1, 2006	Noninvasive Multi-Parameter Patient Monitor	MLR.013A
11	11/366,208	Mar. 1, 2006	Noninvasive Multi-Parameter Patient Monitor	MLR.014A
12	12/056,179	Mar. 26, 2008	Multiple Wavelength Optical Sensor	MLR.015A
13	12/082,810	Apr. 14, 2008	Optical Sensor Assembly	MLR.015A2

The present application incorporates the foregoing disclosures herein by reference.

BACKGROUND

Spectroscopy is a common technique for measuring the concentration of organic and some inorganic constituents of a solution. The theoretical basis of this technique is the Beer-Lambert law, which states that the concentration c_i of an absorbent in solution can be determined by the intensity of light transmitted through the solution, knowing the path-length d_λ, the intensity of the incident light $I_{\theta,\lambda}$, and the extinction coefficient $\varepsilon_{i,\lambda}$ at a particular wavelength λ. In generalized form, the Beer-Lambert law is expressed as:

$$I_\lambda = I_{0,\lambda} e^{-d_\lambda \cdot \mu_{a,\lambda}} \tag{1}$$

$$\mu_{a,\lambda} = \sum_{i=1}^{n} \varepsilon_{i,\lambda} \cdot c_i \tag{2}$$

where, $\mu_{a,\lambda}$ is the bulk absorption coefficient and represents the probability of absorption per unit length. The minimum number of discrete wavelengths that are required to solve EQS. 1-2 are the number of significant absorbers that are present in the solution.

A practical application of this technique is pulse oximetry, which utilizes a noninvasive sensor to measure oxygen saturation (SpO_2) and pulse rate. In general, the sensor has light emitting diodes (LEDs) that transmit optical radiation of red and infrared wavelengths into a tissue site and a detector that responds to the intensity of the optical radiation after absorption (e.g., by transmission or transreflectance) by pulsatile arterial blood flowing within the tissue site. Based on this response, a processor determines measurements for SpO_2, pulse rate, and can output representative plethysmographic waveforms. Thus, "pulse oximetry" as used herein encompasses its broad ordinary meaning known to one of skill in the art, which includes at least those noninvasive

procedures for measuring parameters of circulating blood through spectroscopy. Moreover, "plethysmograph" as used herein (commonly referred to as "photoplethysmograph"), encompasses its broad ordinary meaning known to one of skill in the art, which includes at least data representative of a change in the absorption of particular wavelengths of light as a function of the changes in body tissue resulting from pulsing blood. Pulse oximeters capable of reading through motion induced noise are available from Masimo Corporation ("Masimo") of Irvine, Calif. Moreover, portable and other oximeters capable of reading through motion induced noise are disclosed in at least U.S. Pat. Nos. 6,770,028, 6,658,276, 6,157,850, 6,002,952 5,769,785, and 5,758,644, which are owned by Masimo and are incorporated by reference herein. Such reading through motion oximeters have gained rapid acceptance in a wide variety of medical applications, including surgical wards, intensive care and neonatal units, general wards, home care, physical training, and virtually all types of monitoring scenarios.

SUMMARY

There is a need to noninvasively measure multiple physiological parameters, other than, or in addition to, oxygen saturation and pulse rate. For example, hemoglobin species that are also significant under certain circumstances are carboxyhemoglobin and methemoglobin. Other blood parameters that may be measured to provide important clinical information are fractional oxygen saturation, total hemoglobin (Hbt), bilirubin and blood glucose, to name a few.

One aspect of a physiological sensor is light emitting sources, each activated by addressing at least one row and at least one column of an electrical grid. The light emitting sources transmit light having multiple wavelengths and a detector is responsive to the transmitted light after attenuation by body tissue.

Another aspect of a physiological sensor is light emitting sources capable of transmitting light having multiple wavelengths. Each of the light emitting sources includes a first contact and a second contact. The first contacts of a first set of the light emitting sources are in communication with a first conductor and the second contacts of a second set of the light emitting sources are in communication with a second conductor. A detector is capable of detecting the transmitted light attenuated by body tissue and outputting a signal indicative of at least one physiological parameter of the body tissue. At least one light emitting source of the first set and at least one light emitting source of the second set are not common to the first and second sets. Further, each of the first set and the second set comprises at least two of the light emitting sources.

A further aspect of a physiological sensor sequentially addresses light emitting sources using conductors of an electrical grid so as to emit light having multiple wavelengths that when attenuated by body tissue is indicative of at least one physiological characteristic. The emitted light is detected after attenuation by body tissue.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a perspective view of a physiological measurement system utilizing a multiple wavelength sensor;

FIGS. **2**A-C are perspective views of multiple wavelength sensor embodiments;

FIG. **3** is a general block diagram of a multiple wavelength sensor and sensor controller;

FIG. **4** is an exploded perspective view of a multiple wavelength sensor embodiment;

FIG. **5** is a general block diagram of an emitter assembly;

FIG. **6** is a perspective view of an emitter assembly embodiment;

FIG. **7** is a general block diagram of an emitter array;

FIG. **8** is a schematic diagram of an emitter array embodiment;

FIG. **9** is a general block diagram of equalization;

FIGS. **10**A-D are block diagrams of various equalization embodiments;

FIGS. **11**A-C are perspective views of an emitter assembly incorporating various equalization embodiments;

FIG. **12** is a general block diagram of an emitter substrate;

FIGS. **13-14** are top and detailed side views of an emitter substrate embodiment;

FIG. **15-16** are top and bottom component layout views of an emitter substrate embodiment;

FIG. **17** is a schematic diagram of an emitter substrate embodiment;

FIG. **18** is a plan view of an inner layer of an emitter substrate embodiment;

FIG. **19** is a general block diagram of an interconnect assembly in relationship to other sensor assemblies;

FIG. **20** is a block diagram of an interconnect assembly embodiment;

FIG. **21** is a partially-exploded perspective view of a flex circuit assembly embodiment of an interconnect assembly;

FIG. **22** is a top plan view of a flex circuit;

FIG. **23** is an exploded perspective view of an emitter portion of a flex circuit assembly;

FIG. **24** is an exploded perspective view of a detector assembly embodiment;

FIGS. **25-26** are block diagrams of adjacent detector and stacked detector embodiments;

FIG. **27** is a block diagram of a finger clip embodiment of an attachment assembly;

FIG. **28** is a general block diagram of a detector pad;

FIGS. **29**A-B are perspective views of detector pad embodiments;

FIGS. **30**A-H are perspective bottom, perspective top, bottom, back, top, side cross sectional, side, and front cross sectional views of an emitter pad embodiment;

FIGS. **31**A-H are perspective bottom, perspective top, top, back, bottom, side cross sectional, side, and front cross sectional views of a detector pad embodiment;

FIGS. **32**A-H are perspective bottom, perspective top, top, back, bottom, side cross sectional, side, and front cross sectional views of a shoe box;

FIGS. **33**A-H are perspective bottom, perspective top, top, back, bottom, side cross sectional, side, and front cross sectional views of a slim-finger emitter pad embodiment;

FIGS. **34**A-H are perspective bottom, perspective top, top, back, bottom, side cross sectional, side, and front cross sectional views of a slim-finger detector pad embodiment;

FIGS. **35**A-B are plan and cross sectional views, respectively, of a spring assembly embodiment;

FIGS. **36**A-C are top, perspective and side views of a finger clip spring;

FIGS. **37**A-D are top, back, bottom, and side views of a spring plate;

FIGS. **38**A-D are front cross sectional, bottom, front and side cross sectional views of an emitter-pad shell;

FIGS. **39**A-D are back, top, front and side cross sectional views of a detector-pad shell;

FIG. **40** is a general block diagram of a monitor and a sensor;

FIGS. **41**A-C are schematic diagrams of grid drive embodiments for a sensor having back-to-back diodes and an information element;

FIG. **42** is a schematic diagrams of a grid drive embodiment for an information element;

FIGS. **43**A-C are schematic diagrams for grid drive readable information elements;

FIGS. **44**A-B are cross sectional and side cut away views of a sensor cable;

FIG. **45** is a block diagram of a sensor controller embodiment; and

FIG. **46** is a detailed exploded perspective view of a multiple wavelength sensor embodiment.

DETAILED DESCRIPTION

Overview

In this application, reference is made to many blood parameters. Some references that have common shorthand designations are referenced through such shorthand designations. For example, as used herein, HbCO designates carboxyhemoglobin, HbMet designates methemoglobin, and Hbt designates total hemoglobin. Other shorthand designations such as COHb, MetHb, and tHb are also common in the art for these same constituents. These constituents are generally reported in terms of a percentage, often referred to as saturation, relative concentration or fractional saturation. Total hemoglobin is generally reported as a concentration in g/dL. The use of the particular shorthand designators presented in this application does not restrict the term to any particular manner in which the designated constituent is reported.

FIG. **1** illustrates a physiological measurement system **10** having a monitor **100** and a multiple wavelength sensor assembly **200** with enhanced measurement capabilities as compared with conventional pulse oximetry. The physiological measurement system **10** allows the monitoring of a person, including a patient. In particular, the multiple wavelength sensor assembly **200** allows the measurement of blood constituent and related parameters in addition to oxygen saturation and pulse rate. Alternatively, the multiple wavelength sensor assembly **200** allows the measurement of oxygen saturation and pulse rate with increased accuracy or robustness as compared with conventional pulse oximetry.

In one embodiment, the sensor assembly **200** is configured to plug into a monitor sensor port **110**. Monitor keys **160** provide control over operating modes and alarms, to name a few. A display **170** provides readouts of measured parameters, such as oxygen saturation, pulse rate, HbCO and HbMet to name a few.

FIG. **2**A illustrates a multiple wavelength sensor assembly **200** having a sensor **400** adapted to attach to a tissue site, a sensor cable **4400** and a monitor connector **210**. In one embodiment, the sensor **400** is incorporated into a reusable finger clip adapted to removably attach to, and transmit light through, a fingertip. The sensor cable **4400** and monitor connector **210** are integral to the sensor **400**, as shown. In alternative embodiments, the sensor **400** may be configured separately from the cable **4400** and connector **210**.

FIGS. **2**B-C illustrate alternative sensor embodiments, including a sensor **401** (FIG. **2**B) partially disposable and partially reusable (resposable) and utilizing an adhesive attachment mechanism. Also shown is a sensor **402** (FIG. **2**C) being disposable and utilizing an adhesive attachment mechanism. In other embodiments, a sensor may be configured to attach to various tissue sites other than a finger, such as a foot or an ear. Also a sensor may be configured as a reflectance or transflectance device that attaches to a forehead or other tissue surface.

FIG. **3** illustrates a sensor assembly **400** having an emitter assembly **500**, a detector assembly **2400**, an interconnect assembly **1900** and an attachment assembly **2700**. The emitter assembly **500** responds to drive signals received from a sensor controller **4500** in the monitor **100** via the cable **4400** so as to transmit optical radiation having a plurality of wavelengths into a tissue site. The detector assembly **2400** provides a sensor signal to the monitor **100** via the cable **4400** in response to optical radiation received after attenuation by the tissue site. The interconnect assembly **1900** provides electrical communication between the cable **4400** and both the emitter assembly **500** and the detector assembly **2400**. The attachment assembly **2700** attaches the emitter assembly **500** and detector assembly **2400** to a tissue site, as described above. The emitter assembly **500** is described in further detail with respect to FIG. **5**, below. The interconnect assembly **1900** is described in further detail with respect to FIG. **19**, below. The detector assembly **2400** is described in further detail with respect to FIG. **24**, below. The attachment assembly **2700** is described in further detail with respect to FIG. **27**, below.

FIG. **4** illustrates a sensor **400** embodiment that removably attaches to a fingertip. The sensor **400** houses a multiple wavelength emitter assembly **500** and corresponding detector assembly **2400**. A flex circuit assembly **1900** mounts the emitter and detector assemblies **500**, **2400** and interconnects them to a multi-wire sensor cable **4400**. Advantageously, the sensor **400** is configured in several respects for both wearer comfort and parameter measurement performance. The flex circuit assembly **1900** is configured to mechanically decouple the cable **4400** wires from the emitter and detector assemblies **500**, **2400** to reduce pad stiffness and wearer discomfort. The pads **3000**, **3100** are mechanically decoupled from shells **3800**, **3900** to increase flexibility and wearer comfort. A spring **3600** is configured in hinged shells **3800**, **3900** so that the pivot point of the finger clip is well behind the fingertip, improving finger attachment and more evenly distributing the clip pressure along the finger.

As shown in FIG. **4**, the detector pad **3100** is structured to properly position a fingertip in relationship to the detector assembly **2400**. The pads have flaps that block ambient light. The detector assembly **2400** is housed in an enclosure so as to reduce light piping from the emitter assembly to the detector assembly without passing through fingertip tissue. These and other features are described in detail below. Specifically, emitter assembly embodiments are described with respect to FIGS. **5-18**. Interconnect assembly embodiments, including the flexible circuit assembly **1900**, are described with respect to FIGS. **19-23**. Detector assembly embodiments are described with respect to FIGS. **24-26**. Attachment assembly embodiments are described with respect to FIGS. **27-39**.

Emitter Assembly

FIG. **5** illustrates an emitter assembly **500** having an emitter array **700**, a substrate **1200** and equalization **900**. The emitter array **700** has multiple light emitting sources, each activated by addressing at least one row and at least one column of an electrical grid. The light emitting sources are capable of transmitting optical radiation having multiple wavelengths. The equalization **900** accounts for differences in tissue attenuation of the optical radiation across the multiple wavelengths so as to at least reduce wavelength-dependent variations in detected intensity. The substrate **1200** provides a physical mount for the emitter array and

emitter-related equalization and a connection between the emitter array and the interconnection assembly. Advantageously, the substrate **1200** also provides a bulk temperature measurement so as to calculate the operating wavelengths for the light emitting sources. The emitter array **700** is described in further detail with respect to FIG. **7**, below. Equalization is described in further detail with respect to FIG. **9**, below. The substrate **1200** is described in further detail with respect to FIG. **12**, below.

FIG. **6** illustrates an emitter assembly **500** embodiment having an emitter array **700**, an encapsulant **600**, an optical filter **1100** and a substrate **1200**. Various aspects of the emitter assembly **500** are described with respect to FIGS. **7-18**, below. The emitter array **700** emits optical radiation having multiple wavelengths of predetermined nominal values, advantageously allowing multiple parameter measurements. In particular, the emitter array **700** has multiple light emitting diodes (LEDs) **710** that are physically arranged and electrically connected in an electrical grid to facilitate drive control, equalization, and minimization of optical pathlength differences at particular wavelengths. The optical filter **1100** is advantageously configured to provide intensity equalization across a specific LED subset. The substrate **1200** is configured to provide a bulk temperature of the emitter array **700** so as to better determine LED operating wavelengths.

Emitter Array

FIG. **7** illustrates an emitter array **700** having multiple light emitters (LE) **710** capable of emitting light **702** having multiple wavelengths into a tissue site **1**. Row drivers **4530** and column drivers **4560** are electrically connected to the light emitters **710** and activate one or more light emitters **710** by addressing at least one row **720** and at least one column **740** of an electrical grid. In one embodiment, the light emitters **710** each include a first contact **712** and a second contact **714**. The first contact **712** of a first subset **730** of light emitters is in communication with a first conductor **720** of the electrical grid. The second contact **714** of a second subset **750** of light emitters is in communication with a second conductor **740**. Each subset comprises at least two light emitters, and at least one of the light emitters of the first and second subsets **730**, **750** are not in common. A detector **2400** is capable of detecting the emitted light **702** and outputting a sensor signal **2500** responsive to the emitted light **702** after attenuation by the tissue site **1**. As such, the sensor signal **2500** is indicative of at least one physiological parameter corresponding to the tissue site **1**, as described above.

FIG. **8** illustrates an emitter array **700** having LEDs **801** connected within an electrical grid of n rows and m columns totaling n+m drive lines **4501**, **4502**, where n and m integers greater than one. The electrical grid advantageously minimizes the number of drive lines required to activate the LEDs **801** while preserving flexibility to selectively activate individual LEDs **801** in any sequence and multiple LEDs **801** simultaneously. The electrical grid also facilitates setting LED currents so as to control intensity at each wavelength, determining operating wavelengths and monitoring total grid current so as to limit power dissipation. The emitter array **700** is also physically configured in rows **810**. This physical organization facilitates clustering LEDs **801** according to wavelength so as to minimize pathlength variations and facilitates equalization of LED intensities.

As shown in FIG. **8**, one embodiment of an emitter array **700** comprises up to sixteen LEDs **801** configured in an electrical grid of four rows **810** and four columns **820**. Each of the four row drive lines **4501** provide a common anode connection to four LEDs **801**, and each of the four column drive lines **4502** provide a common cathode connection to four LEDs **801**. Thus, the sixteen LEDs **801** are advantageously driven with only eight wires, including four anode drive lines **812** and four cathode drive lines **822**. This compares favorably to conventional common anode or cathode LED configurations, which require more drive lines. In a particular embodiment, the emitter array **700** is partially populated with eight LEDs having nominal wavelengths as shown in TABLE 1. Further, LEDs having wavelengths in the range of 610-630 nm are grouped together in the same row. The emitter array **700** is adapted to a physiological measurement system **10** (FIG. **1**) for measuring HbCO and/or METHb in addition to S_pO_2 and pulse rate.

TABLE 1

Nominal LED Wavelengths

LED	λ	Row	Col
D1	630	1	1
D2	620	1	2
D3	610	1	3
D4		1	4
D5	700	2	1
D6	730	2	2
D7	660	2	3
D8	805	2	4
D9		3	1
D10		3	2
D11		3	3
D12	905	3	4
D13		4	1
D14		4	2
D15		4	3
D16		4	4

Also shown in FIG. **8**, row drivers **4530** and column drivers **4560** located in the monitor **100** selectively activate the LEDs **801**. In particular, row and column drivers **4530**, **4560** function together as switches to Vcc and current sinks, respectively, to activate LEDs and as switches to ground and Vcc, respectively, to deactivate LEDs. This push-pull drive configuration advantageously prevents parasitic current flow in deactivated LEDs. In a particular embodiment, only one row drive line **4501** is switched to Vcc at a time. One to four column drive lines **4502**, however, can be simultaneously switched to a current sink so as to simultaneously activate multiple LEDs within a particular row. Activation of two or more LEDs of the same wavelength facilitates intensity equalization, as described with respect to FIGS. **9-11**, below. LED drivers are described in further detail with respect to FIG. **45**, below.

Although an emitter assembly is described above with respect to an array of light emitters each configured to transmit optical radiation centered around a nominal wavelength, in another embodiment, an emitter assembly advantageously utilizes one or more tunable broadband light sources, including the use of filters to select the wavelength, so as to minimize wavelength-dependent pathlength differences from emitter to detector. In yet another emitter assembly embodiment, optical radiation from multiple emitters each configured to transmit optical radiation centered around a nominal wavelength is funneled to a tissue site point so as to minimize wavelength-dependent pathlength differences. This funneling may be accomplish with fiberoptics or mirrors, for example. In further embodiments, the LEDs **801** can be configured with alternative orientations with correspondingly different drivers among various other configurations of LEDs, drivers and interconnecting conductors.

Equalization

FIG. **9** illustrate a physiological parameter measurement system **10** having a controller **4500**, an emitter assembly **500**, a detector assembly **2400** and a front-end **4030**. The emitter assembly **500** is configured to transmit optical radiation having multiple wavelengths into the tissue site **1**. The detector assembly **2400** is configured to generate a sensor signal **2500** responsive to the optical radiation after tissue attenuation. The front-end **4030** conditions the sensor signal **2500** prior to analog-to-digital conversion (ADC).

FIG. **9** also generally illustrates equalization **900** in a physiological measurement system **10** operating on a tissue site **1**. Equalization encompasses features incorporated into the system **10** in order to provide a sensor signal **2500** that falls well within the dynamic range of the ADC across the entire spectrum of emitter wavelengths. In particular, equalization compensates for the imbalance in tissue light absorption due to Hb and HbO_2 **910**. Specifically, these blood constituents attenuate red wavelengths greater than IR wavelengths. Ideally, equalization **900** balances this unequal attenuation. Equalization **900** can be introduced anywhere in the system **10** from the controller **4500** to front-end **4000** and can include compensatory attenuation versus wavelength, as shown, or compensatory amplification versus or both.

Equalization can be achieved to a limited extent by adjusting drive currents from the controller **4500** and front-end **4030** amplification accordingly to wavelength so as to compensate for tissue absorption characteristics. Signal demodulation constraints, however, limit the magnitude of these adjustments. Advantageously, equalization **900** is also provided along the optical path from emitters **500** to detector **2400**. Equalization embodiments are described in further detail with respect to FIGS. **10-11**, below.

FIGS. **10**A-D illustrate various equalization embodiments having an emitter array **700** adapted to transmit optical radiation into a tissue site **1** and a detector assembly **2400** adapted to generate a sensor signal **2500** responsive to the optical radiation after tissue attenuation. FIG. **10**A illustrates an optical filter **1100** that attenuates at least a portion of the optical radiation before it is transmitted into a tissue site **1**. In particular, the optical filter **1100** attenuates at least a portion of the IR wavelength spectrum of the optical radiation so as to approximate an equalization curve **900** (FIG. **9**). FIG. **10**B illustrates an optical filter **1100** that attenuates at least a portion of the optical radiation after it is attenuated by a tissue site **1**, where the optical filter **1100** approximates an equalization curve **900** (FIG. **9**).

FIG. **10**C illustrates an emitter array **700** where at least a portion of the emitter array generates one or more wavelengths from multiple light emitters **710** of the same wavelength. In particular, the same-wavelength light emitters **710** boost at least a portion of the red wavelength spectrum so as to approximately equalize the attenuation curves **910** (FIG. **9**). FIG. **10**D illustrates a detector assembly **2400** having multiple detectors **2610**, **2620** selected so as to equalize the attenuation curves **910** (FIG. **9**). To a limited extent, optical equalization can also be achieved by selection of particular emitter array **700** and detector **2400** components, e.g. LEDs having higher output intensities or detectors having higher sensitivities at red wavelengths. Although equalization embodiments are described above with respect to red and IR wavelengths, these equalization embodiments can be applied to equalize tissue characteristics across any portion of the optical spectrum.

FIGS. **11**A-C illustrates an optical filter **1100** for an emitter assembly **500** that advantageously provides optical equalization, as described above. LEDs within the emitter array **700** may be grouped according to output intensity or wavelength or both. Such a grouping facilitates equalization of LED intensity across the array. In particular, relatively low tissue absorption and/or relatively high output intensity LEDs can be grouped together under a relatively high attenuation optical filter. Likewise, relatively low tissue absorption and/or relatively low output intensity LEDs can be grouped together without an optical filter or under a relatively low or negligible attenuation optical filter. Further, high tissue absorption and/or low intensity LEDs can be grouped within the same row with one or more LEDs of the same wavelength being simultaneously activated, as described with respect to FIG. **10**C, above. In general, there can be any number of LED groups and any number of LEDs within a group. There can also be any number of optical filters corresponding to the groups having a range of attenuation, including no optical filter and/or a "clear" filter having negligible attenuation.

As shown in FIGS. **11**A-C, a filtering media may be advantageously added to an encapsulant that functions both as a cover to protect LEDs and bonding wires and as an optical filter **1100**. In one embodiment, a filtering media **1100** encapsulates a select group of LEDs and a clear media **600** (FIG. **6**) encapsulates the entire array **700** and the filtering media **1000** (FIG. **6**). In a particular embodiment, corresponding to TABLE 1, above, five LEDs nominally emitting at 660-905 nm are encapsulated with both a filtering media **1100** and an overlying clear media **600** (FIG. **6**), i.e. attenuated. In a particular embodiment, the filtering media **1100** is a 40:1 mixture of a clear encapsulant (EPO-TEK OG147-7) and an opaque encapsulate (EPO-TEK OG147) both available from Epoxy Technology, Inc., Billerica, Mass. Three LEDs nominally emitting at 610-630 nm are only encapsulated with the clear media **600** (FIG. **6**), i.e. unattenuated. In alternative embodiments, individual LEDs may be singly or multiply encapsulated according to tissue absorption and/or output intensity. In other alternative embodiments, filtering media may be separately attachable optical filters or a combination of encapsulants and separately attachable optical filters. In a particular embodiment, the emitter assembly **500** has one or more notches along each side proximate the component end **1305** (FIG. **13**) for retaining one or more clip-on optical filters.

Substrate

FIG. **12** illustrates light emitters **710** configured to transmit optical radiation **1201** having multiple wavelengths in response to corresponding drive currents **1210**. A thermal mass **1220** is disposed proximate the emitters **710** so as to stabilize a bulk temperature **1202** for the emitters. A temperature sensor **1230** is thermally coupled to the thermal mass **1220**, wherein the temperature sensor **1230** provides a temperature sensor output **1232** responsive to the bulk temperature **1202** so that the wavelengths are determinable as a function of the drive currents **1210** and the bulk temperature **1202**.

In one embodiment, an operating wavelength Aa of each light emitter **710** is determined according to EQ. 3

$$\lambda_a = f(T_b, I_{drive}, \Sigma I_{drive}) \quad (3)$$

where T_b is the bulk temperature, I_{drive} is the drive current for a particular light emitter, as determined by the sensor controller **4500** (FIG. **45**), described below, and ΣI_{drive} is the total drive current for all light emitters. In another embodiment, temperature sensors are configured to measure the temperature of each light emitter **710** and an operating wavelength λ_a of each light emitter **710** is determined according to EQ. 4

$$\lambda_a = f(T_a, I_{drive}, \Sigma I_{drive}) \quad (4)$$

where T_a is the temperature of a particular light emitter, I_{drive} is the drive current for that light emitter and ΣI_{drive} is the total drive current for all light emitters.

In yet another embodiment, an operating wavelength for each light emitter is determined by measuring the junction voltage for each light emitter **710**. In a further embodiment, the temperature of each light emitter **710** is controlled, such as by one or more Peltier cells coupled to each light emitter **710**, and an operating wavelength for each light emitter **710** is determined as a function of the resulting controlled temperature or temperatures. In other embodiments, the operating wavelength for each light emitter **710** is determined directly, for example by attaching a charge coupled device (CCD) to each light emitter or by attaching a fiberoptic to each light emitter and coupling the fiberoptics to a wavelength measuring device, to name a few.

FIGS. **13-18** illustrate one embodiment of a substrate **1200** configured to provide thermal conductivity between an emitter array **700** (FIG. **8**) and a thermistor **1540** (FIG. **16**). In this manner, the resistance of the thermistor **1540** (FIG. **16**) can be measured in order to determine the bulk temperature of LEDs **801** (FIG. **8**) mounted on the substrate **1200**. The substrate **1200** is also configured with a relatively significant thermal mass, which stabilizes and normalizes the bulk temperature so that the thermistor measurement of bulk temperature is meaningful.

FIGS. **13-14** illustrate a substrate **1200** having a component side **1301**, a solder side **1302**, a component end **1305** and a connector end **1306**. Alignment notches **1310** are disposed between the ends **1305**, **1306**. The substrate **1200** further has a component layer **1401**, inner layers **1402-1405** and a solder layer **1406**. The inner layers **1402-1405**, e.g. inner layer **1402** (FIG. **18**), have substantial metallized areas **1411** that provide a thermal mass **1220** (FIG. **12**) to stabilize a bulk temperature for the emitter array **700** (FIG. **12**). The metallized areas **1411** also function to interconnect component pads **1510** and wire bond pads **1520** (FIG. **15**) to the connector **1530**.

FIGS. **15-16** illustrate a substrate **1200** having component pads **1510** and wire bond pads **1520** at a component end **1305**. The component pads **1510** mount and electrically connect a first side (anode or cathode) of the LEDs **801** (FIG. **8**) to the substrate **1200**. Wire bond pads **1520** electrically connect a second side (cathode or anode) of the LEDs **801** (FIG. **8**) to the substrate **1200**. The connector end **1306** has a connector **1530** with connector pads **1532**, **1534** that mount and electrically connect the emitter assembly **500** (FIG. **23**), including the substrate **1200**, to the flex circuit **2200** (FIG. **22**). Substrate layers **1401-1406** (FIG. **14**) have traces that electrically connect the component pads **1510** and wire bond pads **1520** to the connector **1532-1534**. A thermistor **1540** is mounted to thermistor pads **1550** at the component end **1305**, which are also electrically connected with traces to the connector **1530**. Plated thru holes electrically connect the connector pads **1532**, **1534** on the component and solder sides **1301**, **1302**, respectively.

FIG. **17** illustrates the electrical layout of a substrate **1200**. A portion of the LEDs **801**, including D**1**-D**4** and D**13**-D**16** have cathodes physically and electrically connected to component pads **1510** (FIG. **15**) and corresponding anodes wire bonded to wire bond pads **1520**. Another portion of the LEDs **801**, including D**5**-D**8** and D**9**-D**12**, have anodes physically and electrically connected to component pads **1510** (FIG. **15**) and corresponding cathodes wire bonded to wire bond pads **1520**. The connector **1530** has row pinouts J**21**-J**24**, column pinouts J**31**-J**34** and thermistor pinouts J**40**-J**41** for the LEDs **801** and thermistor **1540**.

Interconnect Assembly

FIG. **19** illustrates an interconnect assembly **1900** that mounts the emitter assembly **500** and detector assembly **2400**, connects to the sensor cable **4400** and provides electrical communications between the cable and each of the emitter assembly **500** and detector assembly **2400**. In one embodiment, the interconnect assembly **1900** is incorporated with the attachment assembly **2700**, which holds the emitter and detector assemblies to a tissue site. An interconnect assembly embodiment utilizing a flexible (flex) circuit is described with respect to FIGS. **20-24**, below.

FIG. **20** illustrates an interconnect assembly **1900** embodiment having a circuit substrate **2200**, an emitter mount **2210**, a detector mount **2220** and a cable connector **2230**. The emitter mount **2210**, detector mount **2220** and cable connector **2230** are disposed on the circuit substrate **2200**. The emitter mount **2210** is adapted to mount an emitter assembly **500** having multiple emitters. The detector mount **2220** is adapted to mount a detector assembly **2400** having a detector. The cable connector **2230** is adapted to attach a sensor cable **4400**. A first plurality of conductors **2040** disposed on the circuit substrate **2200** electrically interconnects the emitter mount **2210** and the cable connector **2230**. A second plurality of conductors **2050** disposed on the circuit substrate **2200** electrically interconnects the detector mount **2220** and the cable connector **2230**. A decoupling **2060** disposed proximate the cable connector **2230** substantially mechanically isolates the cable connector **2230** from both the emitter mount **2210** and the detector mount **2220** so that sensor cable stiffness is not translated to the emitter assembly **500** or the detector assembly **2400**. A shield **2070** is adapted to fold over and shield one or more wires or pairs of wires of the sensor cable **4400**.

FIG. **21** illustrates a flex circuit assembly **1900** having a flex circuit **2200**, an emitter assembly **500** and a detector assembly **2400**, which is configured to terminate the sensor end of a sensor cable **4400**. The flex circuit assembly **1900** advantageously provides a structure that electrically connects yet mechanically isolates the sensor cable **4400**, the emitter assembly **500** and the detector assembly **2400**. As a result, the mechanical stiffness of the sensor cable **4400** is not translated to the sensor pads **3000**, **3100** (FIGS. **30-31**), allowing a comfortable finger attachment for the sensor **200** (FIG. **1**). In particular, the emitter assembly **500** and detector assembly **2400** are mounted to opposite ends **2201**, **2202** (FIG. **22**) of an elongated flex circuit **2200**. The sensor cable **4400** is mounted to a cable connector **2230** extending from a middle portion of the flex circuit **2200**. Detector wires **4470** are shielded at the flex circuit junction by a fold-over conductive ink flap **2240**, which is connected to a cable inner shield **4450**. The flex circuit **2200** is described in further detail with respect to FIG. **22**. The emitter portion of the flex circuit assembly **1900** is described in further detail with respect to FIG. **23**. The detector assembly **2400** is described with respect to FIG. **24**. The sensor cable **4400** is described with respect to FIGS. **44**A-B, below.

FIG. **22** illustrates a sensor flex circuit **2200** having an emitter end **2201**, a detector end **2202**, an elongated interconnect **2204**, **2206** between the ends **2201**, **2202** and a cable connector **2230** extending from the interconnect **2204**, **2206**. The emitter end **2201** forms a "head" having emitter solder pads **2210** for attaching the emitter assembly **500** (FIG. **6**) and mounting ears **2214** for attaching to the emitter pad **3000** (FIG. **30**B), as described below. The detector end **2202** has detector solder pads for attaching the detector **2410** (FIG.

24). The interconnect **2204** between the emitter end **2201** and the cable connector **2230** forms a "neck," and the interconnect **2206** between the detector end **2202** and the cable connector **2230** forms a "tail." The cable connector **2230** forms "wings" that extend from the interconnect **2204**, **2206** between the neck **2204** and tail **2206**. A conductive ink flap **2240** connects to the cable inner shield **4450** (FIGS. **44**A-B) and folds over to shield the detector wires **4470** (FIGS. **44**A-B) soldered to the detector wire pads **2236**. The outer wire pads **2238** connect to the remaining cable wires **4430** (FIGS. **44**A-B). The flex circuit **2200** has top coverlay, top ink, inner coverlay, trace, trace base, bottom ink and bottom coverlay layers.

The flex circuit **2200** advantageously provides a connection between a multiple wire sensor cable **4400** (FIGS. **44**A-B), a multiple wavelength emitter assembly **500** (FIG. **6**) and a detector assembly **2400** (FIG. **24**) without rendering the emitter and detector assemblies unwieldy and stiff. In particular, the wings **2230** provide a relatively large solder pad area **2232** that is narrowed at the neck **2204** and tail **2206** to mechanically isolate the cable **4400** (FIGS. **44**A-B) from the remainder of the flex circuit **2200**. Further, the neck **2206** is folded (see FIG. **4**) for installation in the emitter pad **3000** (FIGS. **30**A-H) and acts as a flexible spring to further mechanically isolate the cable **4400** (FIGS. **44**A-B) from the emitter assembly **500** (FIG. **4**). The tail **2206** provides an integrated connectivity path between the detector assembly **2400** (FIG. **24**) mounted in the detector pad **3100** (FIGS. **31**A-H) and the cable connector **2230** mounted in the opposite emitter pad **3000** (FIGS. **30**A-H).

FIG. **23** illustrates the emitter portion of the flex circuit assembly **1900** (FIG. **21**) having the emitter assembly **500**. The emitter assembly connector **1530** is attached to the emitter end **2210** of the flex circuit **2200** (FIG. **22**). In particular, reflow solder **2330** connects thru hole pads **1532**, **1534** of the emitter assembly **500** to corresponding emitter pads **2310** of the flex circuit **2200** (FIG. **22**).

FIG. **24** illustrates a detector assembly **2400** including a detector **2410**, solder pads **2420**, copper mesh tape **2430**, an EMI shield **2440** and foil **2450**. The detector **2410** is soldered **2460** chip side down to detector solder pads **2420** of the flex circuit **2200**. The detector solder joint and detector ground pads **2420** are wrapped with the Kapton tape **2470**. EMI shield tabs **2442** are folded onto the detector pads **2420** and soldered. The EMI shield walls are folded around the detector **2410** and the remaining tabs **2442** are soldered to the back of the EMI shield **2440**. The copper mesh tape **2430** is cut to size and the shielded detector and flex circuit solder joint are wrapped with the copper mesh tape **2430**. The foil **2450** is cut to size with a predetermined aperture **2452**. The foil **2450** is wrapped around shielded detector with the foil side in and the aperture **2452** is aligned with the EMI shield grid **2444**.

Detector Assembly

FIG. **25** illustrates an alternative detector assembly **2400** embodiment having adjacent detectors. Optical radiation having multiple wavelengths generated by emitters **700** is transmitted into a tissue site **1**. Optical radiation at a first set of wavelengths is detected by a first detector **2510**, such as, for example, a Si detector. Optical radiation at a second set of wavelengths is detected by a second detector **2520**, such as, for example, a GaAs detector.

FIG. **26** illustrates another alternative detector assembly **2400** embodiment having stacked detectors coaxial along a light path. Optical radiation having multiple wavelengths generated by emitters **700** is transmitted into a tissue site **1**. Optical radiation at a first set of wavelengths is detected by a first detector **2610**. Optical radiation at a second set of wavelengths passes through the first detector **2610** and is detected by a second detector **2620**. In a particular embodiment, a silicon (Si) detector and a gallium arsenide (GaAs) detector are used. The Si detector is placed on top of the GaAs detector so that light must pass through the Si detector before reaching the GaAs detector. The Si detector can be placed directly on top of the GaAs detector or the Si and GaAs detector can be separated by some other medium, such as a transparent medium or air. In another particular embodiment, a germanium detector is used instead of the GaAs detector. Advantageously, the stacked detector arrangement minimizes error caused by pathlength differences as compared with the adjacent detector embodiment.

Finger Clip

FIG. **27** illustrates a finger clip embodiment **2700** of a physiological sensor attachment assembly. The finger clip **2700** is configured to removably attach an emitter assembly **500** (FIG. **6**) and detector assembly **2400** (FIG. **24**), interconnected by a flex circuit assembly **1900**, to a fingertip. The finger clip **2700** has an emitter shell **3800**, an emitter pad **3000**, a detector pad **2800** and a detector shell **3900**. The emitter shell **3800** and the detector shell **3900** are rotatably connected and urged together by the spring assembly **3500**. The emitter pad **3000** is fixedly retained by the emitter shell. The emitter assembly **500** (FIG. **6**) is mounted proximate the emitter pad **3000** and adapted to transmit optical radiation having a plurality of wavelengths into fingertip tissue. The detector pad **2800** is fixedly retained by the detector shell **3900**. The detector assembly **3500** is mounted proximate the detector pad **2800** and adapted to receive the optical radiation after attenuation by fingertip tissue.

FIG. **28** illustrates a detector pad **2800** advantageously configured to position and comfortably maintain a fingertip relative to a detector assembly for accurate sensor measurements. In particular, the detector pad has fingertip positioning features including a guide **2810**, a contour **2820** and a stop **2830**. The guide **2810** is raised from the pad surface **2803** and narrows as the guide **2810** extends from a first end **2801** to a second end **2802** so as to increasingly conform to a fingertip as a fingertip is inserted along the pad surface **2803** from the first end **2801**. The contour **2820** has an indentation defined along the pad surface **2803** generally shaped to conform to a fingertip positioned over a detector aperture **2840** located within the contour **2820**. The stop **2830** is raised from the pad surface **2803** so as to block the end of a finger from inserting beyond the second end **2802**. FIGS. **29**A-B illustrate detector pad embodiments **3100**, **3400** each having a guide **2810**, a contour **2820** and a stop **2830**, described in further detail with respect to FIGS. **31** and **34**, respectively.

FIGS. **30**A-H illustrate an emitter pad **3000** having emitter pad flaps **3010**, an emitter window **3020**, mounting pins **3030**, an emitter assembly cavity **3040**, isolation notches **3050**, a flex circuit notch **3070** and a cable notch **3080**. The emitter pad flaps **3010** overlap with detector pad flaps **3110** (FIGS. **31**A-H) to block ambient light. The emitter window **3020** provides an optical path from the emitter array **700** (FIG. **8**) to a tissue site. The mounting pins **3030** accommodate apertures in the flex circuit mounting ears **2214** (FIG. **22**), and the cavity **3040** accommodates the emitter assembly **500** (FIG. **21**). Isolation notches **3050** mechanically decouple the shell attachment **3060** from the remainder of the emitter pad **3000**. The flex circuit notch **3070** accommodates the flex circuit tail **2206** (FIG. **22**) routed to the detector pad **3100** (FIGS. **31**A-H). The cable notch **3080**

accommodates the sensor cable **4400** (FIGS. **44**A-B). FIGS. **33**A-H illustrate an alternative slim finger emitter pad **3300** embodiment.

FIGS. **31**A-H illustrate a detector pad **3100** having detector pad flaps **3110**, a shoe box cavity **3120** and isolation notches **3150**. The detector pad flaps **3110** overlap with emitter pad flaps **3010** (FIGS. **30**A-H), interleaving to block ambient light. The shoe box cavity **3120** accommodates a shoe box **3200** (FIG. **32**A-H) described below. Isolation notches **3150** mechanically decouple the attachment points **3160** from the remainder of the detector pad **3100**. FIGS. **34**A-H illustrate an alternative slim finger detector pad **3400** embodiment.

FIGS. **32**A-H illustrate a shoe box **3200** that accommodates the detector assembly **2400** (FIG. **24**). A detector window **3210** provides an optical path from a tissue site to the detector **2410** (FIG. **24**). A flex circuit notch **3220** accommodates the flex circuit tail **2206** (FIG. **22**) routed from the emitter pad **3000** (FIGS. **30**A-H). In one embodiment, the shoe box **3200** is colored black or other substantially light absorbing color and the emitter pad **3000** and detector pad **3100** are each colored white or other substantially light reflecting color.

FIGS. **35-37** illustrate a spring assembly **3500** having a spring **3600** configured to urge together an emitter shell **3800** (FIG. **46**) and a detector shell **3900**. The detector shell is rotatably connected to the emitter shell. The spring is disposed between the shells **3800**, **3900** and adapted to create a pivot point along a finger gripped between the shells that is substantially behind the fingertip. This advantageously allows the shell hinge **3810**, **3910** (FIGS. **38-39**) to expand so as to distribute finger clip force along the inserted finger, comfortably keeping the fingertip in position over the detector without excessive force.

As shown in FIGS. **36**A-C, the spring **3600** has coils **3610**, an emitter shell leg **3620** and a detector shell leg **3630**. The emitter shell leg **3620** presses against the emitter shell **3800** (FIGS. **38**A-D) proximate a grip **3820** (FIGS. **38**A-D). The detector shell legs **3630** extend along the detector shell **3900** (FIGS. **39**A-D) to a spring plate **3700** (FIGS. **37**A-D) attachment point. The coil **3610** is secured by hinge pins **410** (FIG. **46**) and is configured to wind as the finger clip is opened, reducing its diameter and stress accordingly.

As shown in FIGS. **37**A-D the spring plate **3700** has attachment apertures **3710**, spring leg slots **3720**, and a shelf **3730**. The attachment apertures **3710** accept corresponding shell posts **3930** (FIGS. **39**A-D) so as to secure the spring plate **3700** to the detector shell **3900** (FIG. **39**A-D). Spring legs **3630** (FIG. **36**A-C) are slidably anchored to the detector shell **3900** (FIG. **39**A-D) by the shelf **3730**, advantageously allowing the combination of spring **3600**, shells **3800**, **3900** and hinges **3810**, **3910** to adjust to various finger sizes and shapes.

FIGS. **38-39** illustrate the emitter and detector shells **3800**, **3900**, respectively, having hinges **3810**, **3910** and grips **3820**, **3920**. Hinge apertures **3812**, **3912** accept hinge pins **410** (FIG. **46**) so as to create a finger clip. The detector shell hinge aperture **3912** is elongated, allowing the hinge to expand to accommodate a finger.

Monitor And Sensor

FIG. **40** illustrates a monitor **100** and a corresponding sensor assembly **200**, as described generally with respect to FIGS. **1-3**, above. The sensor assembly **200** has a sensor **400** and a sensor cable **4400**. The sensor **400** houses an emitter assembly **500** having emitters responsive to drivers within a sensor controller **4500** so as to transmit optical radiation into a tissue site. The sensor **400** also houses a detector assembly **2400** that provides a sensor signal **2500** responsive to the optical radiation after tissue attenuation. The sensor signal **2500** is filtered, amplified, sampled and digitized by the front-end **4030** and input to a DSP (digital signal processor) **4040**, which also commands the sensor controller **4500**. The sensor cable **4400** electrically communicates drive signals from the sensor controller **4500** to the emitter assembly **500** and a sensor signal **2500** from the detector assembly **2400** to the front-end **4030**. The sensor cable **4400** has a monitor connector **210** that plugs into a monitor sensor port **110**.

In one embodiment, the monitor **100** also has a reader **4020** capable of obtaining information from an information element (IE) in the sensor assembly **200** and transferring that information to the DSP **4040**, to another processor or component within the monitor **100**, or to an external component or device that is at least temporarily in communication with the monitor **100**. In an alternative embodiment, the reader function is incorporated within the DSP **4040**, utilizing one or more of DSP I/O, ADC, DAC features and corresponding processing routines, as examples.

In one embodiment, the monitor connector **210** houses the information element **4000**, which may be a memory device or other active or passive electrical component. In a particular embodiment, the information element **4000** is an EPROM, or other programmable memory, or an EEPROM, or other reprogrammable memory, or both. In an alternative embodiment, the information element **4000** is housed within the sensor **400**, or an information element **4000** is housed within both the monitor connector **4000** and the sensor **400**. In yet another embodiment, the emitter assembly **500** has an information element **4000**, which is read in response to one or more drive signals from the sensor controller **4500**, as described with respect to FIGS. **41-43**, below. In a further embodiment, a memory information element is incorporated into the emitter array **700** (FIG. **8**) and has characterization information relating to the LEDs **801** (FIG. **8**). In one advantageous embodiment, trend data relating to slowly varying parameters, such as perfusion index, HbCO or METHb, to name a few, are stored in an IE memory device, such as EEPROM.

Back-to-Back LEDs

FIGS. **41-43** illustrate alternative sensor embodiments. A sensor controller **4500** configured to activate an emitter array **700** (FIG. **7**) arranged in an electrical grid, is described with respect to FIG. **7**, above. Advantageously, a sensor controller **4500** so configured is also capable of driving a conventional two-wavelength (red and IR) sensor **4100** having back-to-back LEDs **4110**, **4120** or an information element **4300** or both.

FIG. **41**A illustrates a sensor **4100** having an electrical grid **4130** configured to activate light emitting sources by addressing at least one row conductor and at least one column conductor. A first LED **4110** and a second LED **4120** are configured in a back-to-back arrangement so that a first contact **4152** is connected to a first LED **4110** cathode and a second LED **4120** anode and a second contact **4154** is connected to a first LED **4110** anode and a second LED **4120** cathode. The first contact **4152** is in communications with a first row conductor **4132** and a first column conductor **4134**. The second contact is in communications with a second row conductor **4136** and a second column conductor **4138**. The first LED **4110** is activated by addressing the first row conductor **4132** and the second column conductor **4138**. The second LED **4120** is activated by addressing the second row conductor **4136** and the first column conductor **4134**.

FIG. **41**B illustrates a sensor cable **4400** embodiment capable of communicating signals between a monitor **100**

and a sensor **4100**. The cable **4400** has a first row input **4132**, a first column input **4134**, a second row input **4136** and a second column input **4138**. A first output **4152** combines the first row input **4132** and the first column input **4134**. A second output **4154** combines a second row input **4136** and second column input **4138**.

FIG. **41**C illustrates a monitor **100** capable of communicating drive signals to a sensor **4100**. The monitor **4400** has a first row signal **4132**, a first column signal **4134**, a second row signal **4136** and a second column signal **4138**. A first output signal **4152** combines the first row signal **4132** and the first column signal **4134**. A second output signal **4154** combines a second row signal **4136** and second column signal **4138**.

Information Elements

FIGS. **42-43** illustrate information element **4200-4300** embodiments in communications with emitter array drivers configured to activate light emitters connected in an electrical grid. The information elements are configured to provide information as DC values, AC values or a combination of DC and AC values in response corresponding DC, AC or combination DC and AC electrical grid drive signals. FIG. **42** illustrates information element embodiment **4200** advantageously driven directly by an electrical grid having rows **710** and columns **720**. In particular, the information element **4200** has a series connected resistor R_2 **4210** and diode **4220** connected between a row line **710** and a column line **720** of an electrical grid. In this manner, the resistor R_2 value can be read in a similar manner that LEDs **810** (FIG. **8**) are activated. The diode **4220** is oriented, e.g. anode to row and cathode to column as the LEDs so as to prevent parasitic currents from unwanted activation of LEDs **810** (FIG. **8**).

FIGS. **43**A-C illustrate other embodiments where the value of R_1 is read with a DC grid drive current and a corresponding grid output voltage level. In other particular embodiments, the combined values of R_1, R_2 and C or, alternatively, R_1, R_2 and L are read with a varying (AC) grid drive currents and a corresponding grid output voltage waveform. As one example, a step in grid drive current is used to determine component values from the time constant of a corresponding rise in grid voltage. As another example, a sinusoidal grid drive current is used to determine component values from the magnitude or phase or both of a corresponding sinusoidal grid voltage. The component values determined by DC or AC electrical grid drive currents can represent sensor types, authorized suppliers or manufacturers, emitter wavelengths among others. Further, a diode D (FIG. **43**C) can be used to provide one information element reading R_1 at one drive level or polarity and another information element reading, combining R_1 and R_2, at a second drive level or polarity, i.e. when the diode is forward biased.

Passive information element **4300** embodiments may include any of various combinations of resistors, capacitors or inductors connected in series and parallel, for example. Other information element **4300** embodiments connected to an electrical grid and read utilizing emitter array drivers incorporate other passive components, active components or memory components, alone or in combination, including transistor networks, PROMs, ROMs, EPROMs, EEPROMs, gate arrays and PLAs to name a few.

Sensor Cable

FIGS. **44**A-B illustrate a sensor cable **4400** having an outer jacket **4410**, an outer shield **4420**, multiple outer wires **4430**, an inner jacket **4440**, an inner shield **4450**, a conductive polymer **4460** and an inner twisted wire pair **4470**. The outer wires **4430** are advantageously configured to compactly carry multiple drive signals to the emitter array **700** (FIG. **7**). In one embodiment, there are twelve outer wires **4430** corresponding to four anode drive signals **4501** (FIG. **45**), four cathode drive signals **4502** (FIG. **45**), two thermistor pinouts **1450** (FIG. **15**) and two spares. The inner twisted wire pair **4470** corresponds to the sensor signal **2500** (FIG. **25**) and is extruded within the conductive polymer **4460** so as to reduce triboelectric noise. The shields **4420**, **4450** and the twisted pair **4470** boost EMI and crosstalk immunity for the sensor signal **2500** (FIG. **25**).

Controller

FIG. **45** illustrates a sensor controller **4500** located in the monitor **100** (FIG. **1**) and configured to provide anode drive signals **4501** and cathode drive signals **4502** to the emitter array **700** (FIG. **7**). The DSP (digital signal processor) **4040**, which performs signal processing functions for the monitor, also provides commands **4042** to the sensor controller **4500**. These commands determine drive signal **4501**, **4502** levels and timing. The sensor controller **4500** has a command register **4510**, an anode selector **4520**, anode drivers **4530**, current DACs (digital-to-analog converters) **4540**, a current multiplexer **4550**, cathode drivers **4560**, a current meter **4570** and a current limiter **4580**. The command register **4510** provides control signals responsive to the DSP commands **4042**. In one embodiment, the command register **4510** is a shift register that loads serial command data **4042** from the DSP **4040** and synchronously sets output bits that select or enable various functions within the sensor controller **4500**, as described below.

As shown in FIG. **45**, the anode selector **4520** is responsive to anode select **4516** inputs from the command register **4510** that determine which emitter array row **810** (FIG. **8**) is active. Accordingly, the anode selector **4520** sets one of the anode on **4522** outputs to the anode drivers **4530**, which pulls up to Vcc one of the anode outputs **4501** to the emitter array **700** (FIG. **8**).

Also shown in FIG. **45**, the current DACs **4540** are responsive to command register data **4519** that determines the currents through each emitter array column **820** (FIG. **8**). In one embodiment, there are four, 12-bit DACs associated with each emitter array column **820** (FIG. **8**), sixteen DACs in total. That is, there are four DAC outputs **4542** associated with each emitter array column **820** (FIG. **8**) corresponding to the currents associated with each row **810** (FIG. **8**) along that column **820** (FIG. **8**). In a particular embodiment, all sixteen DACs **4540** are organized as a single shift register, and the command register **4510** serially clocks DAC data **4519** into the DACs **4540**. A current multiplexer **4550** is responsive to cathode on **4518** inputs from the command register **4510** and anode on **4522** inputs from the anode selector **4520** so as to convert the appropriate DAC outputs **4542** to current set **4552** inputs to the cathode drivers **4560**. The cathode drivers **4560** are responsive to the current set **4552** inputs to pull down to ground one to four of the cathode outputs **4502** to the emitter array **700** (FIG. **8**).

The current meter **4570** outputs a current measure **4572** that indicates the total LED current driving the emitter array **700** (FIG. **8**). The current limiter **4580** is responsive to the current measure **4572** and limits specified by the command register **4510** so as to prevent excessive power dissipation by the emitter array **700** (FIG. **8**). The current limiter **4580** provides an enable **4582** output to the anode selector **4520**. A Hi Limit **4512** input specifies the higher of two preset current limits. The current limiter **4580** latches the enable **4582** output in an off condition when the current limit is

exceeded, disabling the anode selector **4520**. A trip reset **4514** input resets the enable **4582** output to re-enable the anode selector **4520**.

Sensor Assembly

As shown in FIG. **46**, the sensor **400** has an emitter shell **3800**, an emitter pad **3000**, a flex circuit assembly **2200**, a detector pad **3100** and a detector shell **3900**. A sensor cable **4400** attaches to the flex circuit assembly **2200**, which includes a flex circuit **2100**, an emitter assembly **500** and a detector assembly **2400**. The portion of the flex circuit assembly **2200** having the sensor cable **4400** attachment and emitter assembly **500** is housed by the emitter shell **3800** and emitter pad **3000**. The portion of the flex circuit assembly **2200** having the detector assembly **2400** is housed by the detector shell **3900** and detector pad **3100**. In particular, the detector assembly **2400** inserts into a shoe **3200**, and the shoe **3200** inserts into the detector pad **3100**. The emitter shell **3800** and detector shell **3900** are fastened by and rotate about hinge pins **410**, which insert through coils of a spring **3600**. The spring **3600** is held to the detector shell **3900** with a spring plate **3700**. A finger stop **450** attaches to the detector shell. In one embodiment, a silicon adhesive **420** is used to attach the pads **3000**, **3100** to the shells **3800**, **3900**, a silicon potting compound **430** is used to secure the emitter and detector assemblies **500**, **2400** within the pads **3000**, **3100**, and a cyanoacrylic adhesive **440** secures the sensor cable **4400** to the emitter shell **3800**.

A multiple wavelength sensor has been disclosed in detail in connection with various embodiments. These embodiments are disclosed by way of examples only and are not to limit the scope of the claims that follow. One of ordinary skill in art will appreciate many variations and modifications.

What is claimed is:

1. A physiological monitoring device comprising:

at least three LEDs recessed into a cavity, the at least three LEDs configured to emit light of at least three different wavelengths;

at least one detector configured to detect at least a portion of the light emitted from the at least three LEDs after at least a portion of the light has been attenuated by tissue, the at least one detector configured to output at least one signal responsive to the detected light;

a light block surrounding the at least one detector, the light block comprising a shoebox structure configured to recess the at least one detector into the shoebox structure, wherein the shoebox structure is at least partially formed of a black material, wherein a top of the shoebox structure includes only one opening through which light is configured to pass, the opening comprising an area smaller than a detection surface area of the at least one detector; and

a processor configured to receive and process one or more signals responsive to the outputted at least one signal and determine a physiological parameter of a user responsive to the one or more signals.

2. The device of claim **1**, wherein the at least three LEDs comprises at least eight LEDs.

3. The device of claim **2**, wherein the at least eight LEDs comprises at least two LEDs of the same wavelength.

4. The device of claim **1**, wherein the at least three LEDs comprises at least twelve LEDs.

5. The device of claim **1**, wherein at least two LEDs of the at least three LEDs are configured for concurrent activation.

6. The device of claim **1**, wherein the at least one detector comprises at least two detectors.

7. The device of claim **1**, wherein the at least one detector comprises at least two detectors of different types.

8. The device of claim **1**, wherein the opening provides an optical path from the tissue to the at least one detector.

9. The device of claim **1**, wherein the opening provides an optical path from the at least three LEDs to the tissue.

10. A physiological monitoring device comprising:

at least three LEDs recessed into a cavity, the at least three LEDs configured to emit light of at least three different wavelengths;

at least one detector configured to detect at least a portion of the light emitted from the at least three LEDs after at least a portion of the light has been attenuated by tissue, the at least one detector configured to output at least one signal responsive to the detected light;

an electromagnetic interference shield positioned between the at least three LEDs and the at least one detector;

a light block surrounding the at least one detector, the light block at least partially formed of black materials, the light block comprising a base, four side walls and a top forming an enclosure, wherein the light block comprises a window, the window having an area smaller than a detection surface area of the at least one detector; and

a processor configured to receive and process one or more signals responsive to the outputted at least one signal and determine a physiological parameter of a user responsive to the one or more signals.

11. The device of claim **10**, wherein the at least three LEDs comprises at least eight LEDs.

12. The device of claim **11**, wherein the at least eight LEDs comprises at least two LEDs of the same wavelength.

13. The device of claim **10**, wherein the at least three LEDs comprises at least twelve LEDs.

14. The device of claim **10**, wherein at least two LEDs of the at least three LEDs are configured for concurrent activation.

15. The device of claim **10**, wherein the at least one detector comprises at least two detectors.

16. The device of claim **10**, wherein the at least one detector comprises at least two detectors of different types.

17. The device of claim **10**, wherein the window provides an optical path from the tissue to the at least one detector.

18. The method of claim **10**, wherein the window provides an optical path from the at least three LEDs to the tissue.

19. A method for determining a physiological parameter of a living patient, the method comprising:

positioning a sensor with respect to body tissue of a living patient, the sensor comprising at least three LEDs, at least one detector, and a light block at least partially surrounding the at least one detector, wherein a top of the light block comprises only one opening through which light is configured to pass;

activating the at least three LEDs such that at least three wavelengths of light are emitted from the at least three LEDs;

detecting, at the at least one detector, at least a portion of the light emitted from the at least three LEDs after at least a portion of the light has been attenuated by the body tissue and passed through the opening of the top of the light block, wherein the at least one detector outputs at least one signal responsive to the detected light; and

determining a physiological parameter of the living patient responsive to the outputted at least one signal.

20. The method of claim **19**, wherein an area of the opening is smaller than a detection surface area of the at least one detector.

21. The method of claim **19**, wherein the light block is formed of black materials and further comprises a base, side walls, and a top forming an enclosure, and wherein the at least one detector is positioned in the enclosure.

22. The method of claim **19**, wherein said activating the at least three LEDs comprises concurrently activating at least two LEDs of the at least three LEDs.

23. The method of claim **19**, wherein the at least three LEDs comprises at least eight LEDs.

24. The method of claim **23**, wherein the at least eight LEDs comprises at least two LEDs of the same wavelength.

25. The method of claim **19**, wherein the at least three LEDs comprises at least twelve LEDs.

26. The method of claim **19**, wherein the at least one detector comprises at least two detectors.

27. The method of claim **19**, wherein the at least one detector comprises at least two detectors of different types.

28. The method of claim **19**, wherein the at least a portion of the light passes through the opening after it interacts with the body tissue.

29. The method of claim **19**, wherein the at least a portion of the light passes through the opening before it interacts with the body tissue.

* * * * *

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO. : 10,984,911 B2
APPLICATION NO. : 17/028655
DATED : April 20, 2021
INVENTOR(S) : Robert A. Smith

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

On the Title Page

On page 2, in Column 1, item (63), Related U.S. Application Data, Line 5, delete "13/776,085," and insert -- 13/776,065, --.

On page 10, in Column 1, item (56), U.S. Patent Documents, Line 72, delete "Tani" and insert -- Tari --.

On page 13, in Column 2, item (56), Other Publications, Lines 62-63, delete "Jul. 17 2006;" and insert -- Jul. 17, 2006; --.

In the Specification

In Column 2, Line 12, delete "$I_{\theta,\lambda}$," and insert -- $I_{0,\lambda}$, --.

In Column 2, Line 23, delete "where," and insert -- where --.

In Column 4, Line 17, delete "FIG." and insert -- FIGS. --.

In Column 8, Line 13, delete "S_pO_2" and insert -- SpO_2 --.

In Column 10, Line 55, delete "Aa" and insert -- λa --.

In Column 15, Line 9, delete "(FIG." and insert -- (FIGS. --.

In Column 15, Line 48, delete "(FIG." and insert -- (FIGS. --.

In Column 15, Line 49, delete "(FIG." and insert -- (FIGS. --.

In Column 15, Line 50, delete "(FIG." and insert -- (FIGS. --.

Signed and Sealed this
Twenty-ninth Day of June, 2021

Drew Hirshfeld
Performing the Functions and Duties of the
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office

In the Claims

In Column 20, Line 46, Claim 18, delete “The method of claim” and insert -- The device of claim --.

Excerpts of File History of U.S. Patent No. 10,984,911

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/028,655	09/22/2020	Robert A. Smith	MLR.002C6	3736

20995 7590 11/09/2020

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IRVINE, CA 92614

EXAMINER	
FARDANESH, MARJAN	

ART UNIT	PAPER NUMBER
3791	

NOTIFICATION DATE	DELIVERY MODE
11/09/2020	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

efiling@knobbe.com
jayna.cartee@knobbe.com

Office Action Summary	Application No. 17/028,655	Applicant(s) Smith et al.	
	Examiner MARJAN FARDANESH	Art Unit 3791	AIA (FITF) Status No

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2a)☐ This action is **FINAL.** 2b) ☑ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims*

5) ☐ Claim(s) _____ is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6) ☐ Claim(s) _____ is/are allowed.

7) ☑ Claim(s) 21-49 is/are rejected.

8) ☐ Claim(s) _____ is/are objected to.

9) ☐ Claim(s) _____ are subject to restriction and/or election requirement

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to **PPHfeedback@uspto.gov.**

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☑ The drawing(s) filed on 09/22/2020 is/are: a)☑ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

a)☐ All b)☐ Some** c)☐ None of the:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

** See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☑ Notice of References Cited (PTO-892)

2) ☑ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b) Paper No(s)/Mail Date 09/22/2020.

3) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date _____.

4) ☐ Other: _____.

DETAILED ACTION

Notice of Pre-AIA or AIA Status

1. The present application is being examined under the pre-AIA first to invent provisions.

Claim Rejections - 35 USC § 103

2. The following is a quotation of pre-AIA 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 21-49 is/are rejected under pre-AIA 35 U.S.C. 103(a) as being unpatentable over Schulz et al. (USPN 6,580,086) in view of USPN (5,355,880)

Regarding claims 21, 30, 39-41, Schulz et al. discloses a physiological monitoring device comprising: one or more LEDs recessed into a cavity, the one or more LEDs configured to emit light of at least three different wavelengths (Col.5 line 50-Col.6 line 60); at least one detector configured to detect at least a portion of the light emitted from the one or more after at least a portion of the light has been attenuated by tissue, the at least one detector configured to output at least one signal responsive to the detected light (Col.5 line 50-Col.6 line 60); a light block surrounding the at least one detector, the light block comprising a shoebox structure configured to recess the at least one detector into the shoebox structure, wherein the shoebox structure is formed of a black material, the shoebox structure further comprising a window on a top portion of the shoebox structure, the window comprising an area smaller than a detection surface

area of the at least one detector (as shown in the figure below, Col.10 lines 30-50; as shown in the figure below the window is smaller than the entire detection surface area of the detector 105); and a processor configured to receive and process one or more signals responsive to the outputted at least one signal and determine a physiological parameter of a user responsive to the one or more signals (Col.12 line 20-Col.13 line 3). While Schulz et al. discloses one or more LEDs, Schulz fails to disclose at least three LEDs. Thomas et al. discloses reliable non-invasive measurement of blood gases including light emitting diodes and detector (figure 48, Col.28 line 50-Col.29 line 60). Therefore, it would have been obvious to one of ordinary skills in the art at the time the invention was made to incorporate the several light sources of Thomas et al. into the device of Schulz et al., since such modification provides several light sources in order to obtain multiple physiological parameters.

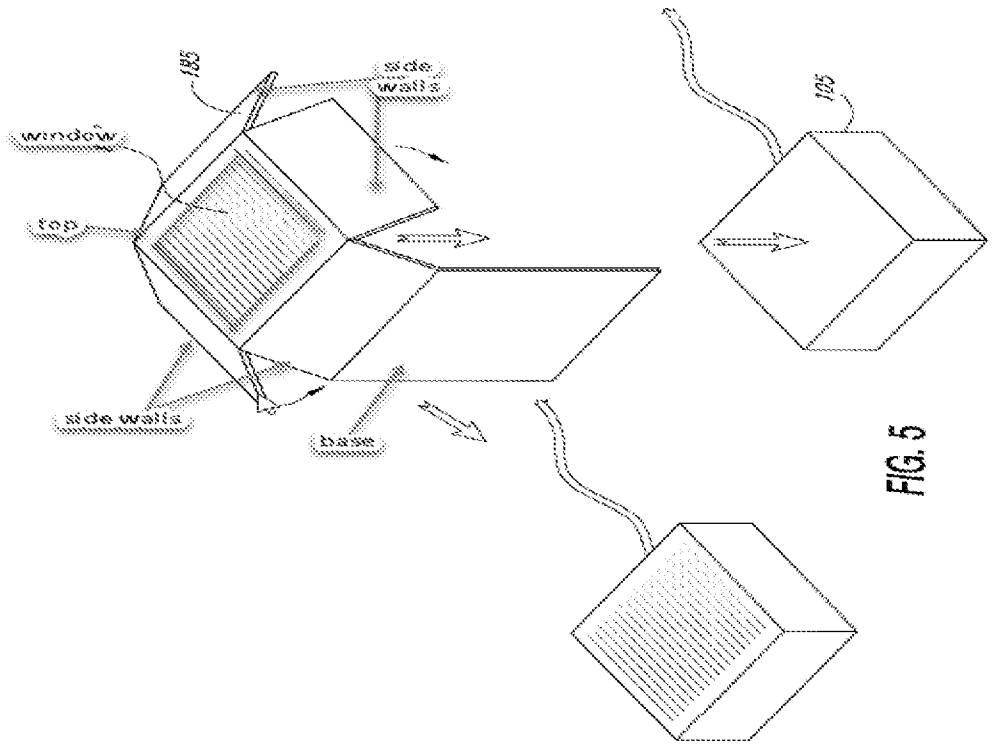

FIG. 5

Regarding claim 22, Schulz et al. in view of Thomas et al. discloses the at least three LEDs comprises at least eight LEDs (Thomas et al. figure 48, Col.28 line 50-Col.29 line 60).

Regarding claim 23, Schulz et al. in view of Thomas et al. discloses the at least eight LEDs comprises at least two LEDs of the same wavelength (Thomas et al. figure 48, Col.28 line 50-Col.29 line 60).

Regarding claim 24, Schulz et al. in view of Thomas et al. discloses the at least three LEDs comprises at least twelve LEDs (Thomas et al. Col.15 lines 2-6, Col.17 line 10-Col.18 line 15, Col.28 line 50-Col.29 line 60).

Regarding claim 25, Schulz et al. in view of Thomas et al. discloses at least two LEDs of the at least three LEDs are configured for concurrent activation (Thomas et al. Col.15 lines 2-6, Col.17 line 10-Col.18 line 15, Col.28 line 50-Col.29 line 60).

Regarding claim 26, Schulz et al. in view of Thomas et al. discloses the at least one detector comprises at least two detectors (Thomas et al. array detector, Col.15 lines 2-6, Col.17 line 10-Col.18 line 15, Col.28 line 50-Col.29 line 60).

Regarding claims 27, 47, Schulz et al. in view of Thomas et al. discloses the at least one detector comprises at least two detectors of different types (Thomas et al. array detector, Col.15 lines 2-6, Col.17 line 10-Col.18 line 15, Col.28 line 50-Col.29 line 60).

Regarding claim 28, Schulz et al. in view of Thomas et al. discloses the window provides an optical path from the tissue to the at least one detector (as shown in the figure above and figures 2-3 of Schulz et al.).

Regarding claim 29, Schulz et al. in view of Thomas et al. discloses the window provides an optical path from the at least three LEDs to the tissue (as shown in the figure above and figures 2-3 of Schulz et al.).

Regarding claim 31, Schulz et al. in view of Thomas et al. discloses the at least three LEDs comprises at least eight LEDs (figure 48, Col.28 line 50-Col.29 line 60).

Regarding claim 32, Schulz et al. in view of Thomas et al. discloses the at least eight LEDs comprises at least two LEDs of the same wavelength (figure 48, Col.28 line 50-Col.29 line 60).

Regarding claim 33, 45, Schulz et al. in view of Thomas et al. discloses the at least three LEDs comprises at least twelve LEDs (Thomas et al. Col.15 lines 2-6, Col.17 line 10-Col.18 line 15, Col.28 line 50-Col.29 line 60).

Regarding claims 34, 42, Schulz et al. in view of Thomas et al. discloses at least two LEDs of the at least three LEDs are configured for concurrent activation (Thomas et al. Col.15 lines 2-6, Col.17 line 10-Col.18 line 15, Col.28 line 50-Col.29 line 60).

Regarding claims 35, 46, Schulz et al. in view of Thomas et al. discloses the at least one detector comprises at least two detectors (Thomas et al. array detector, Col.15 lines 2-6, Col.17 line 10-Col.18 line 15, Col.28 line 50-Col.29 line 60).

Regarding claim 36, Schulz et al. in view of Thomas et al. discloses the at least one detector comprises at least two detectors of different types (Thomas et al. array detector, Col.15 lines 2-6, Col.17 line 10-Col.18 line 15, Col.28 line 50-Col.29 line 60).

Regarding claim 37, Schulz et al. in view of Thomas et al. discloses the window provides an optical path from the tissue to the at least one detector(as shown in the figure above and figures 2-3 of Schulz et al.).

Regarding claim 38, Schulz et al. in view of Thomas et al. discloses the window provides an optical path from the at least three LEDs to the tissue (as shown in the figure above and figures 2-3 of Schulz et al.).

Regarding claim 43, Schulz et al. in view of Thomas et al. discloses the at least three LEDs comprises at least eight LEDs (figure 48, Col.28 line 50-Col.29 line 60).

Regarding claim 44, Schulz et al. in view of Thomas et al. discloses the at least eight LEDs comprises at least two LEDs of the same wavelength (figure 48, Col.28 line 50-Col.29 line 60).

Regarding claim 48, Schulz et al. in view of Thomas et al. discloses the at least a portion of the light passes through the window after it interacts with the body tissue (as shown in the figure above and figures 2-3 of Schulz et al.).

Regarding claim 49, Schulz et al. in view of Thomas et al. discloses the at least a portion of the light passes through the window before it interacts with the body tissue (as shown in the figure above and figures 2-3 of Schulz et al.).

Conclusion

4. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Fuse et al. (5,313,940) discloses a finger clip sensor including emitters and detectors and shoe-like light block wherein the detector(s) is located inside the shoe-like light block (figures 3-7, Col.3 line 5-Col.4 line 20).

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to MARJAN FARDANESH whose telephone number is (571)270-5508. The examiner can normally be reached on Monday-Friday 9:00-17:00.

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at http://www.uspto.gov/interviewpractice.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jacqueline Cheng can be reached on (571)272-5596. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see https://ppair-my.uspto.gov/pair/PrivatePair. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/MARJAN FARDANESH/
Examiner, Art Unit 3791

MLR.002C6 PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Inventor	:	Robert A. Smith
App. No.	:	17/028655
Filed	:	September 22, 2020
For	:	MULTIPLE WAVELENGTH SENSOR EMITTERS
Examiner	:	Fardanesh, Marian
Art Unit	:	3791
Conf. No.	:	3736

RESPONSE TO OFFICE ACTION DATED NOVEMBER 9, 2020

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Commissioner:

In response to the Non-Final Office Action dated November 9, 2020, please consider the following:

Amendments to the Claims are reflected in the listing of claims which begins on page 2 of this paper.

Summary of Interview begins on page 6 of this paper.

Remarks/Arguments begin on page 7 of this paper.

Application No.: **17/028655**
Filing Date: **September 22, 2020**

AMENDMENTS TO THE CLAIMS

1-20. (Canceled)

21. (**Currently Amended**) A physiological monitoring device comprising:

at least three LEDs recessed into a cavity, the at least three LEDs configured to emit light of at least three different wavelengths;

at least one detector configured to detect at least a portion of the light emitted from the at least three LEDs after at least a portion of the light has been attenuated by tissue, the at least one detector configured to output at least one signal responsive to the detected light;

a light block surrounding the at least one detector, the light block comprising a shoebox structure configured to recess the at least one detector into the shoebox structure, wherein the shoebox structure is at least partially formed of a black material, wherein a top of the shoebox structure includes only one opening through which light is configured to pass~~further comprising a window on a top portion of the shoebox structure~~, the opening ~~window~~ comprising an area smaller than a detection surface area of the at least one detector; and

a processor configured to receive and process one or more signals responsive to the outputted at least one signal and determine a physiological parameter of a user responsive to the one or more signals.

22. (Previously Presented) The device of Claim 21, wherein the at least three LEDs comprises at least eight LEDs.

23. (Previously Presented) The device of Claim 22, wherein the at least eight LEDs comprises at least two LEDs of the same wavelength.

24. (Previously Presented) The device of Claim 21, wherein the at least three LEDs comprises at least twelve LEDs.

25. (Previously Presented) The device of Claim 21, wherein at least two LEDs of the at least three LEDs are configured for concurrent activation.

26. (Previously Presented) The device of Claim 21, wherein the at least one detector comprises at least two detectors.

27. (Previously Presented) The device of Claim 21, wherein the at least one detector comprises at least two detectors of different types.

28. (**Currently Amended**) The device of Claim 21, wherein the ~~window~~ opening provides an optical path from the tissue to the at least one detector.

29. (**Currently Amended**) The device of Claim 21, wherein the opening ~~window~~ provides an optical path from the at least three LEDs to the tissue.

30. (**Currently Amended**) A physiological monitoring device comprising:

at least three LEDs recessed into a cavity, the at least three LEDs configured to emit light of at least three different wavelengths;

at least one detector configured to detect at least a portion of the light emitted from the at least three LEDs after at least a portion of the light has been attenuated by tissue, the at least one detector configured to output at least one signal responsive to the detected light;

an electromagnetic interference shield positioned between the at least three LEDs and the at least one detector;

a light block surrounding the at least one detector, the light block at least partially formed of black materials, the light block comprising a base, four side walls and a top forming an enclosure, wherein the light block comprises a window, the window having an area smaller than a detection surface area of the at least one detector; and

a processor configured to receive and process one or more signals responsive to the outputted at least one signal and determine a physiological parameter of a user responsive to the one or more signals.

31. (Previously Presented) The device of Claim 30, wherein the at least three LEDs comprises at least eight LEDs.

32. (Previously Presented) The device of Claim 31, wherein the at least eight LEDs comprises at least two LEDs of the same wavelength.

33. (Previously Presented) The device of Claim 30, wherein the at least three LEDs comprises at least twelve LEDs.

34. (Previously Presented) The device of Claim 30, wherein at least two LEDs of the at least three LEDs are configured for concurrent activation.

35. (Previously Presented) The device of Claim 30, wherein the at least one detector comprises at least two detectors.

36. (Previously Presented) The device of Claim 30, wherein the at least one detector comprises at least two detectors of different types.

37. (Previously Presented) The device of Claim 30, wherein the window provides an optical path from the tissue to the at least one detector.

38. (Previously Presented) The method of Claim 38, wherein the window provides an optical path from the at least three LEDs to the tissue.

39. (**Currently Amended**) A method for determining a physiological parameter of a living patient, the method comprising:

positioning a sensor with respect to body tissue of a living patient, the sensor comprising at least three LEDs, at least one detector, and a light block at least partially surrounding the at least one detector, wherein a top of the light block comprises only one opening through which light is configured to pass~~comprising a window~~;

activating the at least three LEDs such that at least three wavelengths of light are emitted from the at least three LEDs;

detecting, at the at least one detector, at least a portion of the light emitted from the at least three LEDs after at least a portion of the light has been attenuated by the body tissue and passed through the opening~~window~~ of the top of the light block, wherein the at least one detector outputs at least one signal responsive to the detected light; and

determining a physiological parameter of the living patient responsive to the outputted at least one signal.

40. (**Currently Amended**) The method of Claim 39, wherein an area of the ~~window~~ opening is smaller than a detection surface area of the at least one detector.

41. (Previously Presented) The method of Claim 39, wherein the light block is formed of black materials and further comprises a base, side walls, and a top forming an enclosure, and wherein the at least one detector is positioned in the enclosure.

42. (Previously Presented) The method of Claim 39, wherein said activating the at least three LEDs comprises concurrently activating at least two LEDs of the at least three LEDs.

43. (Previously Presented) The method of Claim 39, wherein the at least three LEDs comprises at least eight LEDs.

44. (Previously Presented) The method of Claim 43, wherein the at least eight LEDs comprises at least two LEDs of the same wavelength.

45. (Previously Presented) The method of Claim 39, wherein the at least three LEDs comprises at least twelve LEDs.

46. (Previously Presented) The method of Claim 39, wherein the at least one detector comprises at least two detectors.

47. (Previously Presented) The method of Claim 39, wherein the at least one detector comprises at least two detectors of different types.

48. **Currently Amended**) The method of Claim 39, wherein the at least a portion of the light passes through the ~~window~~ opening after it interacts with the body tissue.

49. (**Currently Amended**) The method of Claim 39, wherein the at least a portion of the light passes through the opening ~~window~~ before it interacts with the body tissue.

Application No.: **17/028655**
Filing Date: **September 22, 2020**

SUMMARY OF INTERVIEW

Attendees, Date and Type of Interview

A telephonic interview (the "Interview") was conducted on February 5, 2021 and attended by Examiner Fardanesh, and Applicant's representative David Grant (reg. no. 74,373).

Identification of Claims Discussed

All claims

Identification of Prior Art Discussed

- U.S. Patent No. 6,580,086 to Schulz
- U.S. Patent No. 5,355,880 to Thomas

Proposed Amendments, Principal Arguments, and Other Matters

Examiners and Applicant's representatives discussed the technology disclosed in the specification as well as the outstanding rejections under § 103.

Results of Interview

Without acquiescence and solely to advance prosecution of the present application, Applicant's representative proposed amendments substantially similar to those presented herein. Examiner Fardanesh agreed that the claims overcome the outstanding rejections under § 103. No agreement was reached with respect to allowability or with respect to the outstanding rejections under § 112.

REMARKS

This paper is filed in response to the Office Action March 20, 2020 (hereinafter "Office Action") in connection with the above-referenced application. In response to the Office Action, Applicant has amended Claims 21, 28-30, 39, 40, 48, and 49. No claims were canceled or added. Accordingly, Claims 21-49 are pending and are presented for further examination. No new subject matter is believed to have been added to the present application by way of the amendments. Example support for the amendments can be found at least in paragraphs [0087] and [0092] and Figures 24 and 46. For the following reasons, Applicant respectfully requests reconsideration of the claims of the present application.

Rejections under 35 U.S.C. § 103

Claims 21-49 were rejected under 35 U.S.C. § 103 as allegedly being unpatentable over U.S. Patent No. 6,580,086 to Schulz et al. (hereinafter "Schulz") in view of U.S. Patent No. 5,355,880 to Thomas et al. (hereinafter "Thomas"). Applicant respectfully traverses each of these rejections, the characterizations of the pending claims, and each and every implicit and/or explicit potential reliance on Official Notice. In view of the foregoing amendments and for at least the reasons set forth below, Applicant respectfully disagrees and requests reconsideration of the aforementioned claims.

Claims 21-29

Claim 21 has been amended as recited above and substantially as discussed during the Interview. For example, Claim 21 has been amended to recite, in part:

> at least three LEDs recessed into a cavity, the at least three LEDs configured to emit light of at least three different wavelengths;
>
> at least one detector configured to detect at least a portion of the light emitted from the at least three LEDs after at least a portion of the light has been attenuated by tissue, the at least one detector configured to output at least one signal responsive to the detected light;
>
> a light block surrounding the at least one detector, the light block comprising a shoebox structure configured to recess the at least one detector into the shoebox structure, wherein the shoebox structure is at least partially formed of a black material, wherein a top of the shoebox structure includes only one opening through which light is configured to pass, the opening comprising an area

> smaller than a detection surface area of the at least one detector; and
>
> a processor configured to receive and process one or more signals responsive to the outputted at least one signal and determine a physiological parameter of a user responsive to the one or more signals.

As discussed during the interview and agreed to by the Examiner, Shutlz, Thomas, and the other references of record do not teach or make obvious each and every recitation of Claim 21. Accordingly, Applicant requests withdrawal of the rejection of Claim 21 under 35 U.S.C. § 103.

Applicant additionally requests the rejections under 35 U.S.C. § 103 of Claims 21-27, each of which depends either directly or indirectly from Claim 21, be withdrawn at least for reasons similar to those discussed above with respect to Claim 21, and for the unique patentable features recited by each.

Claims 30-38

Claim 30 has been amended as recited above and substantially as discussed during the Interview. For example, Claim 30 has been amended to recite, in part:

> at least three LEDs recessed into a cavity, the at least three LEDs configured to emit light of at least three different wavelengths;
>
> at least one detector configured to detect at least a portion of the light emitted from the at least three LEDs after at least a portion of the light has been attenuated by tissue, the at least one detector configured to output at least one signal responsive to the detected light;
>
> an electromagnetic interference shield positioned between the at least three LEDs and the at least one detector;
>
> a light block surrounding the at least one detector, the light block at least partially formed of black materials, the light block comprising a base, four side walls and a top forming an enclosure, wherein the light block comprises a window, the window having an area smaller than a detection surface area of the at least one detector; and
>
> a processor configured to receive and process one or more signals responsive to the outputted at least one signal and determine a physiological parameter of a user responsive to the one or more signals.

As discussed during the interview and agreed to by the Examiner, Shutlz, Thomas, and the other references of record do not teach or make obvious each and every recitation of Claim 30. Accordingly, Applicant requests withdrawal of the rejection of Claim 30 under 35 U.S.C. § 103.

Applicant additionally requests the rejections under 35 U.S.C. § 103 of Claims 31-38, each of which depends either directly or indirectly from Claim 30, be withdrawn at least for reasons similar to those discussed above with respect to Claim 30, and for the unique patentable features recited by each.

Claims 39-49

Claim 39 has been amended as recited above and substantially as discussed during the Interview. For example, Claim 39 has been amended to recite, in part:

> positioning a sensor with respect to body tissue of a living patient, the sensor comprising at least three LEDs, at least one detector, and a light block at least partially surrounding the at least one detector, wherein a top of the light block comprises only one opening through which light is configured to pass;
>
> activating the at least three LEDs such that at least three wavelengths of light are emitted from the at least three LEDs;
>
> detecting, at the at least one detector, at least a portion of the light emitted from the at least three LEDs after at least a portion of the light has been attenuated by the body tissue and passed through the opening of the top of the light block, wherein the at least one detector outputs at least one signal responsive to the detected light; and
>
> determining a physiological parameter of the living patient responsive to the outputted at least one signal.

As discussed during the interview and agreed to by the Examiner, Shutlz, Thomas, and the other references of record do not teach or make obvious each and every recitation of Claim 39. Accordingly, Applicant requests withdrawal of the rejection of Claim 39 under 35 U.S.C. § 103.

Applicant additionally requests the rejections under 35 U.S.C. § 103 of Claims 30-49, each of which depends either directly or indirectly from Claim 39, be withdrawn at least for reasons similar to those discussed above with respect to Claim 39, and for the unique patentable features recited by each.

No Disclaimer or Disavowals

Applicant respectfully submits that the claims are in condition for allowance. Furthermore, any remarks in support of patentability of one claim should not be imputed to any other claim, even if similar terminology is used. Any remarks referring to only a portion of a claim should not be understood to base patentability on that portion or that the element discussed is essential or critical; rather, patentability must rest on each claim taken as a whole. Applicant respectfully traverses each of the Examiner's rejections and each of the Examiner's assertions regarding what the prior art shows or teaches, even if not expressly discussed herein. Although the present communication may include alterations to the application or claims, or characterizations of claim scope or referenced art, no acquiescence, disclaimer or estoppel is intended or should be implied thereby. Applicant is not conceding in this application that previously pending claims are not patentable over the cited references. Rather, any alterations or characterizations are being made only to expedite prosecution of the present application and are without prejudice to the presentation or assertion, in the future, of claims relating to the same or similar subject matter. Applicant may not have presented in all cases, arguments concerning whether the applied references render the claims anticipated or obvious, and Applicant reserves the right to later submit additional arguments of patentability. Applicant also reserves the right to pursue at a later date any previously pending or other broader or narrower claims that capture any subject matter supported by the present disclosure. Accordingly, reviewers of this or any parent, child, or related prosecution history shall not reasonably infer that Applicant has made any disclaimers or disavowals of any subject matter supported by the present application.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: February 9, 2021

By: /David J. Grant/
David Grant
Registration No. 74,373
Registered Practitioner
202) 640-6400

34072596

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

NOTICE OF ALLOWANCE AND FEE(S) DUE

20995 7590 03/03/2021

KNOBBE MARTENS OLSON & BEAR LLP
2040 MAIN STREET
FOURTEENTH FLOOR
IRVINE, CA 92614

EXAMINER	
FARDANESH, MARJAN	
ART UNIT	PAPER NUMBER
3791	

DATE MAILED: 03/03/2021

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/028,655	09/22/2020	Robert A. Smith	MLR.002C6	3736

TITLE OF INVENTION: MULTIPLE WAVELENGTH SENSOR EMITTERS

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	UNDISCOUNTED	$1200	$0.00	$0.00	$1200	06/03/2021

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the ENTITY STATUS shown above. If the ENTITY STATUS is shown as SMALL or MICRO, verify whether entitlement to that entity status still applies.

If the ENTITY STATUS is the same as shown above, pay the TOTAL FEE(S) DUE shown above.

If the ENTITY STATUS is changed from that shown above, on PART B - FEE(S) TRANSMITTAL, complete section number 5 titled "Change in Entity Status (from status indicated above)".

For purposes of this notice, small entity fees are 1/2 the amount of undiscounted fees, and micro entity fees are 1/2 the amount of small entity fees.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Maintenance fees are due in utility patents issuing on applications filed on or after Dec. 12, 1980. It is patentee's responsibility to ensure timely payment of maintenance fees when due. More information is available at www.uspto.gov/PatentMaintenanceFees.

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), by mail or fax, or via EFS-Web.

By mail, send to: Mail Stop ISSUE FEE
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

By fax, send to: (571)-273-2885

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

20995 7590 03/03/2021

KNOBBE MARTENS OLSON & BEAR LLP
2040 MAIN STREET
FOURTEENTH FLOOR
IRVINE, CA 92614

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

Certificate of Mailing or Transmission

I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being transmitted to the USPTO via EFS-Web or by facsimile to (571) 273-2885, on the date below.

(Typed or printed name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/028,655	09/22/2020	Robert A. Smith	MLR.002C6	3736

TITLE OF INVENTION: MULTIPLE WAVELENGTH SENSOR EMITTERS

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	UNDISCOUNTED	$1200	$0.00	$0.00	$1200	06/03/2021

EXAMINER	ART UNIT	CLASS-SUBCLASS
FARDANESH, MARJAN	3791	600-324000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

❑ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.

❑ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-09 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list

(1) The names of up to 3 registered patent attorneys or agents OR, alternatively,

(2) The name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.

1 _____

2 _____

3 _____

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document must have been previously recorded, or filed for recordation, as set forth in 37 CFR 3.11 and 37 CFR 3.81(a). Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE

(B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent) : ❑ Individual ❑ Corporation or other private group entity ❑ Government

4a. Fees submitted: ❑ Issue Fee ❑ Publication Fee (if required) ❑ Advance Order - # of Copies _____

4b. Method of Payment: *(Please first reapply any previously paid fee shown above)*

❑ Electronic Payment via EFS-Web ❑ Enclosed check ❑ Non-electronic payment by credit card (Attach form PTO-2038)

❑ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment to Deposit Account No. _____

5. **Change in Entity Status** (from status indicated above)

❑ Applicant certifying micro entity status. See 37 CFR 1.29

❑ Applicant asserting small entity status. See 37 CFR 1.27

❑ Applicant changing to regular undiscounted fee status.

NOTE: Absent a valid certification of Micro Entity Status (see forms PTO/SB/15A and 15B), issue fee payment in the micro entity amount will not be accepted at the risk of application abandonment.
NOTE: If the application was previously under micro entity status, checking this box will be taken to be a notification of loss of entitlement to micro entity status.
NOTE: Checking this box will be taken to be a notification of loss of entitlement to small or micro entity status, as applicable.

NOTE: This form must be signed in accordance with 37 CFR 1.31 and 1.33. See 37 CFR 1.4 for signature requirements and certifications.

Authorized Signature _____ Date _____

Typed or printed name _____ Registration No. _____

PTOL-85 Part B (08-18) Approved for use through 01/31/2020 OMB 0651-0033 U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

UNITED STATES PATENT AND TRADEMARK OFFICE

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Alexandria, Virginia 22313-1450
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/028,655	09/22/2020	Robert A. Smith	MLR.002C6	3736

20995 7590 03/03/2021

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2040 MAIN STREET
FOURTEENTH FLOOR
IRVINE, CA 92614

EXAMINER	
FARDANESH, MARJAN	
ART UNIT	PAPER NUMBER
3791	

DATE MAILED: 03/03/2021

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)
(Applications filed on or after May 29, 2000)

The Office has discontinued providing a Patent Term Adjustment (PTA) calculation with the Notice of Allowance.

Section 1(h)(2) of the AIA Technical Corrections Act amended 35 U.S.C. 154(b)(3)(B)(i) to eliminate the requirement that the Office provide a patent term adjustment determination with the notice of allowance. See Revisions to Patent Term Adjustment, 78 Fed. Reg. 19416, 19417 (Apr. 1, 2013). Therefore, the Office is no longer providing an initial patent term adjustment determination with the notice of allowance. The Office will continue to provide a patent term adjustment determination with the Issue Notification Letter that is mailed to applicant approximately three weeks prior to the issue date of the patent, and will include the patent term adjustment on the patent. Any request for reconsideration of the patent term adjustment determination (or reinstatement of patent term adjustment) should follow the process outlined in 37 CFR 1.705.

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

OMB Clearance and PRA Burden Statement for PTOL-85 Part B

The Paperwork Reduction Act (PRA) of 1995 requires Federal agencies to obtain Office of Management and Budget approval before requesting most types of information from the public. When OMB approves an agency request to collect information from the public, OMB (i) provides a valid OMB Control Number and expiration date for the agency to display on the instrument that will be used to collect the information and (ii) requires the agency to inform the public about the OMB Control Number's legal significance in accordance with 5 CFR 1320.5(b).

The information collected by PTOL-85 Part B is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 30 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450. Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Notice of Allowability	Application No. 17/028,655	Applicant(s) Smith et al.	
	Examiner MARJAN FARDANESH	Art Unit 3791	AIA (FITF) Status No

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☑ This communication is responsive to amendments filed on 02/09/2021.
   ☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2. ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

3. ☑ The allowed claim(s) is/are 21-49 . As a result of the allowed claim(s), you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see **http://www.uspto.gov/patents/init_events/pph/index.jsp** or send an inquiry to **PPHfeedback@uspto.gov.**

4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

a) ☐ All b) ☐ Some *c) ☐ None of the:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____ .

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____ .

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☑ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date 02/09/2021.
3. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material _____.
4. ☐ Interview Summary (PTO-413), Paper No./Mail Date. _____.
5. ☐ Examiner's Amendment/Comment
6. ☑ Examiner's Statement of Reasons for Allowance
7. ☐ Other _____.

/MARJAN FARDANESH/ Examiner, Art Unit 3791	/ERIC F WINAKUR/ Primary Examiner, Art Unit 3791

DETAILED ACTION

Notice of Pre-AIA or AIA Status

1. The present application is being examined under the pre-AIA first to invent provisions.

Reasons for Allowance

2. The following is an examiner's statement of reasons for allowance: Schulz et al. (USPN 6,580,086-previously cited) discloses a physiological monitoring device comprising: one or more LEDs recessed into a cavity, the one or more LEDs configured to emit light of at least three different wavelengths (Col.5 line 50-Col.6 line 60); at least one detector configured to detect at least a portion of the light emitted from the one or more after at least a portion of the light has been attenuated by tissue, the at least one detector configured to output at least one signal responsive to the detected light (Col.5 line 50-Col.6 line 60); an electromagnetic interference shield positioned between the LEDs and the at least one detector (Col. 12 line 20-Col. 13 line 3); and a processor configured to receive and process one or more signals responsive to the outputted at least one signal and determine a physiological parameter of a user responsive to the one or more signals (Col. 12 line 20-Col. 13 line 3). While Schulz et al. discloses one or more LEDs, Schulz fails to disclose at least three LEDs. Thomas et al. discloses reliable non-invasive measurement of blood gases including light emitting diodes and detector (figure 48, Col.28 line 50-Col.29 line 60). Therefore, it would have been obvious to one of ordinary skills in the art at the time the invention was made to incorporate the several light sources of Thomas et al. into the device of Schulz et al., since such modification provides several light sources in order to obtain multiple physiological parameters.

However, the combination of Schulz et al. in view of Thomas et al. fails to disclose a light block surrounding the at least one detector, the light block comprising a shoebox structure configured to recess the at least one detector into the shoebox structure, wherein the shoebox structure is formed of a black material, the shoebox structure further comprising a window on a top portion of the shoebox structure, the window comprising an area smaller than a detection surface area of the at least one detector, in combination with remaining claimed features.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MARJAN FARDANESH whose telephone number is (571)270-5508. The examiner can normally be reached on Monday-Friday 9:00-17:00.

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at http://www.uspto.gov/interviewpractice.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jacqueline Cheng can be reached on (571)272-5596. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see https://ppair-my.uspto.gov/pair/PrivatePair. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Examiner, Art Unit 3791

Excerpts of File History of U.S. Patent No. 11,545,263

MLR.002C7 PATENT

RESPONSE TO OFFICE ACTION

First Inventor: Smith, Robert A.	**Conf. No.:** 1571
App. No.: 17/224833	**Filed:** April 7, 2021
Examiner: Liu, Chu Chuan	**Art Unit:** 3791
Title: MULTIPLE WAVELENGTH SENSOR EMITTERS	

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Commissioner:

In response to the non-final Office Action dated March 28, 2022 (hereinafter the "Office Action"), in connection with the above-referenced patent application, please amend the application and consider the remarks that follow.

Amendments to the Claims are reflected in the listing of claims which begins on page 2 of this paper.

Remarks/Arguments begin on page 6 of this paper.

Application No.: **17/224833**
Filing Date: **April 7, 2021**

AMENDMENTS TO THE CLAIMS

1. (Previously Presented) A physiological monitoring device comprising:

at least two LEDs, the at least two LEDs configured to emit light of at least two different wavelengths;

at least one detector configured to detect at least a portion of the light emitted from the at least two LEDs after at least a portion of the light has been attenuated by tissue, the at least one detector configured to output at least one signal responsive to the detected light;

a light block surrounding the at least one detector and configured to be disposed within a housing of the physiological monitoring device, the light block forming a cavity, the light block comprising a light-absorbing material, the light block including only one opening through which light is configured to pass, an area of the opening being smaller than a surface area of a facing surface of the at least one detector, the light absorbing material forming at least an edge of the only one opening; and

a processor configured to receive and process one or more signals responsive to the outputted at least one signal and determine a physiological parameter of a user responsive to the one or more signals.

2. (Original) The physiological monitoring device of Claim 1, wherein the at least two LEDs comprises at least eight LEDs.

3. (Original) The physiological monitoring device of Claim 2, wherein the at least eight LEDs comprises at least two LEDs of the same wavelength.

4. (Original) The physiological monitoring device of Claim 1, wherein the at least two LEDs comprises at least twelve LEDs.

5. (Original) The physiological monitoring device of Claim 1, wherein multiple LEDs of the at least two LEDs are configured for concurrent activation.

6. (Original) The physiological monitoring device of Claim 1, wherein the at least one detector comprises at least two detectors.

7. (Original) The physiological monitoring device of Claim 1, further comprising an electromagnetic interference shield positioned between the at least two LEDs and the at least one detector.

8. (Original) The physiological monitoring device of Claim 1, wherein the light block is a substantially rectangular enclosure.

9. (Original) The physiological monitoring device of Claim 1, wherein the light block comprises a base, a plurality of side walls, and a top.

10. (Previously Presented) The physiological monitoring device of Claim 1, wherein the area of the opening is less than half a surface area of a top of the light block.

11. (Previously Presented) The physiological monitoring device of Claim 1, wherein the opening is screen-less.

12. (Previously Presented) The physiological monitoring device of Claim 1, wherein the light block comprises an aperture sized to accept the at least one detector, wherein the aperture is different from the opening.

13. (Currently Amended) A method for determining a physiological parameter of a living patient, the method comprising:

positioning a sensor with respect to body tissue of a living patient, the sensor comprising at least two LEDs, at least one detector, a light block surrounding the at least one detector, the at least two LEDs configured to emit light of at least two different wavelengths, the light block forming a cavity, the light block comprising a light-absorbing material, the light block including only one opening through which light is configured to pass, an area of the opening being smaller than a surface area of a facing surface of the at least one detector, the light absorbing material forming at least an edge of the only one opening;

activating the at least two LEDs;

detecting, at the at least one detector, at least a portion of the light emitted from the at least two LEDs after at least a portion of the light has been attenuated by the body tissue, passed through a transparent medium, and passed through the opening of the light block, wherein the at least one detector outputs at least one signal responsive to the detected light, wherein the transparent medium is positioned in an optical path between the at least two LEDs and the at least one detector; and

determining a physiological parameter of the living patient responsive to the outputted at least one signal.

14. (Original) The method of Claim 13, wherein the at least two LEDs comprises at least eight LEDs.

15. (Original) The method of Claim 14, wherein the at least eight LEDs comprises at least two LEDs of the same wavelength.

16. (Original) The method of Claim 13, wherein the at least two LEDs comprises at least twelve LEDs.

17. (Original) The method of Claim 13, wherein said activating the at least two LEDs comprises concurrently activating multiple LEDs of the at least two LEDs.

18. (Original) The method of Claim 13, wherein the at least one detector comprises at least two detectors.

19. (Original) The method of Claim 13, wherein the sensor further comprises an electromagnetic interference shield positioned between the at least two LEDs and the at least one detector.

20. (Original) The method of Claim 13, wherein the light block is a substantially rectangular enclosure.

21. (Original) The method of Claim 13, wherein the light block comprises a shoebox structure.

22. (Previously Presented) The method of Claim 13, wherein the opening is screen-less.

23. (Previously Presented) The method of Claim 13, wherein the light block comprises an aperture sized to accept the at least one detector, wherein the aperture is different from the opening.

24. (Previously Presented) A physiological sensor comprising:

a housing;

at least two LEDs, the at least two LEDs configured to emit light of at least two different wavelengths;

at least one detector configured to detect at least a portion of the light emitted from the at least two LEDs after at least a portion of the light has been attenuated by tissue, the at least one detector configured to output at least one signal responsive to the detected light; and

a light block that is at least partially enclosed, the light block surrounding the at least one detector, the light block forming a cavity, the light block comprising a light-

absorbing material, the light block including only one opening through which light is configured to pass, an area of the opening being smaller than a surface area of a facing surface of the at least one detector, the light absorbing material forming at least an edge of the only one opening, and the light block configured to be disposed within the housing.

25. (Original) The sensor of Claim 24, wherein the at least two LEDs comprises at least eight LEDs.

26. (Original) The device of Claim 2, wherein the at least eight LEDs comprises at least two LEDs of the same wavelength.

27. (Canceled)

28. (Original) The sensor of Claim 24, further comprising an electromagnetic interference shield positioned between the at least two LEDs and the at least one detector.

29. (Canceled)

30. (Original) The sensor of Claim 24, wherein the light block comprises a shoebox structure.

31. (Previously Presented) The method of Claim 13, wherein the at least a portion of the light passes through the transparent medium after the at least a portion of the light has been attenuated by the body tissue.

32. (Previously Presented) The method of Claim 13, wherein the light block is configured to be disposed within a housing of the physiological monitoring device.

REMARKS

This paper is filed in response to the Office Action mailed March 28, 2022 (hereinafter "Office Action") in connection with the above-referenced application. In response to the Office Action, Applicant makes the remarks below. Accordingly, Claims 1-26, 28, and 30-32 are pending and presented for further examination. For the following reasons, Applicant respectfully requests reconsideration of the claims of the present application.

Rejections under 35 U.S.C. §§ 102 and 103

Independent Claims 1, 13, and 24 were rejected under 35 U.S.C. § 102 as allegedly being anticipated by U.S. Publication No. 2001/0009265 to Schulz (hereinafter "Schulz"). Dependent Claims 7-12, 19-24, 28, and 30-32 were also rejected under 35 U.S.C. § 102 allegedly anticipated by Schulz. Dependent Claims 2-6, 14-18, 25, and 26 were rejected under U.S.C. § 103 as unpatentable over Schulz in view of various combinations of U.S. Pat. No. 5,203,329 to Takatina (hereinafter "Takatina"), U.S. Pat. No. 5,638,818 to Diab (hereinafter "Diab"), and U.S. Pat. No. 5,752,914 to Delonzor (hereinafter "Delonzor"). Applicant respectfully traverses each of these rejections, the characterizations of the pending claims, and each and every implicit and/or explicit potential reliance on Official Notice. For at least the reasons set forth below, Applicant respectfully disagrees and requests reconsideration of the aforementioned claims.

Independent Claims 1, 13, and 24

Claim 1 recites, *inter alia*,

> "a light block surrounding the at least one detector and configured to be disposed within a housing of the physiological monitoring device, the light block forming a cavity, the light block comprising a light-absorbing material, the light block including only one opening through which light is configured to pass, an area of the opening being smaller than a surface area of a facing surface of the at least one detector, the light absorbing material forming at least an edge of the only one opening."

The Office Action relies on Schulz at reference 116 for the light block feature (*Office Action* at pg. 3). Schulz discloses a lower surface element 116 (*Schulz* at para. [0039]-[0042]) and a detector 105 (*see, e.g. Schulz* at para. [0041]). However, the lower surface element 116 does not appear to surround the detector 105 as recited in Claim 1. The Office Action appears to rely on

Figs. 2, 3, 5, and 6 for this feature (*Office Action* at pg. 3). However, Figs. 2 and 6 do not clearly show this arrangement (for example, it is unclear from the figures if the lower surface element 116 surrounds the detector 105, or is merely located over it or otherwise disposed between the detector 105 and the user's finger). Schulz at Fig. 3 also does not clearly show the lower surface element 116 surrounding the detector 105. In contrast, the detector 105 appears to be located below the lower surface element 116, or within cavity 115b made by cooperating portions of both the lower surface element 116 and the lower housing 106 (*Schulz* at para. [0040]), where neither the lower surface element 116 nor the lower housing 106 surround the detector 105.

Schulz at cited Fig. 5 illustrates a noise shield 185 and does not show the lower surface element 116 at all. Although this noise shield 185 is shown to surround the detector 105, the Office Action has not cited the noise shield as the recited light block element. Moreover, the noise shield 185 includes a grating 187 that "permits light to pass while still blocking electromagnetic energy" (*Schulz* at para. [0051]). Such a grating therefore does not disclose a light block with "only one opening through which light is configured to pass" as recited in Claim 1. The Office Action has therefore failed to show that Schulz discloses a light block with at least the combination of these recited features as discussed above.

Similarly, Claim 13 recites, *inter alia*, "a light block surrounding the at least one detector… [and] comprising a light-absorbing material, the light block including only one opening through which light is configured to pass." Claim 24 also recites, *inter alia*, a "light block surrounding the at least one detector… the light block including only one opening through which light is configured to pass." As discussed above, the Office Action has failed to show at least this combination of features is disclosed in Schulz. Accordingly, Applicant respectfully requests that the rejections of Claims 1, 13, and 24 made under 35 U.S.C § 102 be withdrawn and the claims be allowed.

Dependent Claims

The dependent claims depend directly or indirectly from Claims 1, 13, or 24 and include all limitations therein. As discussed above, the Office Action fails to show that Schulz discloses every recitation. The Office Action has also not shown that Takatina, Diab, or Delonzor disclose these recited features. Therefore, Applicant respectfully submits the dependent claims are patentably distinct from the cited references for at least the reasons set forth above. In addition,

Applicant notes that these claims, when taken in the context of their respective independent claim, set forth a number of recitations that have not been shown by the Office Action to be taught, disclosed, suggested, or rendered obvious by the cited references. Accordingly, Applicant respectfully requests that the rejection of the dependent claims be withdrawn and the claims be allowed.

Double Patenting

The Office Action rejects the claims under the judicially created doctrine of non-statutory, obviousness-type double patenting ("ODP") as unpatentable over U.S. Pat. No. 10,984,911 in view of Schulz. Applicant respectfully requests that the double patenting rejection be reconsidered in view of the remarks regarding Schulz made above. Further, as the Office Action does not indicate that the claims are otherwise allowable, Applicant respectfully requests these rejections be held in abeyance.

No Disclaimers or Disavowals

Although the present communication may include alterations to the application or claims, or characterizations of claim scope or referenced art, Applicant is not conceding in this application that previously pending claims are not patentable. Rather, any alterations or characterizations are being made to facilitate expeditious prosecution of this application. Applicant reserves the right to pursue at a later date any previously pending or other broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child or related prosecution history shall not reasonably infer that Applicant has made any disclaimers or disavowals of any subject matter supported by the present application.

Application No.: **17/224833**
Filing Date: **April 7, 2021**

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: July 28, 2022

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